IDEM Agency-Wide Quality Management Plan

March 2007

Indiana Department of Environmental Management
Indiana Government Center-North
MC 50-01 IGCN 1301
100 N. Senate Ave.
Indianapolis, IN 46204

Indiana Department of Environmental Management (IDEM)
Agency- Wide Quality Management Plan
March 2007 Revision

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Indiana Department of Environmental Management

Thomas W. Easterly, Commissioner — Date: APRIL 24, 2007

Scott J. Nally, Assistant Commissioner
Office of External Affairs — Date: 4/24/07

Niles M. Parker, Director
Planning and Assessment — Date: 4/24/07

David Parry, Quality Assurance Manager — Date: 4/24/07

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U.S. Environmental Protection Agency Region V (U.S. EPA)

Mary A. Gade, Regional Administrator, Region V — Date 4-17-07

Kevin Bolger, Regional Quality Assurance Manager — Date 04/16/07

Stephen Rothblatt, Director
Air and Radiation Division — Date 4/16/2007

Jerri-Anne Garl, Director
Office of Science, Ecosystems and Communities — Date 4/16/07

Walter Kovalik, ~~Associate~~ Assistant Regional
Administrator for Resources Management — Date 4/16/07

for Richard Karl, Director
Superfund Division — Date 4/16/07

for Margaret Guerriero, Director
Waste, Pesticides and Toxics Division — Date 4/16/07

Jo-Lynn Traub, Director
Water Division — Date 4/16/07

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U.S. Environmental Protection Agency EPA Great Lakes National Program Office (GLNPO)

Gary Gulezian, Director
U.S. EPA GLNPO

4/16/2007
Date

Louis Blume, Quality Assurance Manager
U.S. EPA GLNPO

4/16/2007
Date

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Appendix C: IDEM Management Organizational Chart
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Introduction

The Indiana Department of Environmental Management's (IDEM) core mission is to implement federal and state regulations to protect human health and the environment while allowing the environmentally sound operations of industrial, agricultural, commercial and government activities vital to a prosperous economy.

It is IDEM's goal that all Agency decisions be speedy, consistent, transparent (to both stakeholders and the public), predictable, fair, and protective of public health and environment. IDEM needs an efficient quality system to assist in the Agency decision-making process. The more effective IDEM's quality system, the less subjective the decisions it issues.

IDEM's quality system performs the following functions and further improves the existing Agency review chain:

1) Designates staff that develops quality assurance tools and implements quality assurance practices;
2) Promotes quality control evaluations;
3) Standardizes processes in SOPs (Standard Operating Procedures);
4) Documents the institutional knowledge of experienced staff in written SOPs and policies;
5) Ensures that documents and records are prepared and managed in a manner consistent with scientific standards and legal requirements;
6) Focuses on planning the capture of appropriate data to meet established standards; and
7) Relies on frequent quality assurance assessment that results in meaningful changes that further improve the quality system.

IDEM's primary work product is in the form of documents that announce and record an Agency decision. Agency notices of deficient information on an application (Notice of Deficiency, or NOD), draft permits, final permits, certifications, licenses, inspection reports, violation letters, and administrative orders all are examples of "decision-announcing-records". Most Agency decisions are based on subjective, professional judgment. Decisions involving remediation plans, permit issuance, compliance determinations, or the pursuit of enforcement actions are based on the best professional judgment of Agency staff, using the most accurate and readily confirmable data available, to yield decisions that reflect environmentally-sound and widely accepted interpretations of statutes and rules.

Because not all the data available to IDEM during decision-making is verifiable by Agency staff, and because not all the statutes and rules upon which decisions are based cover every possible scenario, interpretation of data, statutes, and/or rules is sometimes a necessary part of the Agency decision-making process. Also, Agency decisions may be appealed by those seeking a different interpretation of the data, statutes and/or rules. This further confirms that Agency decisions are at least somewhat subjective in nature.

A key component of ensuring that each Agency decision is a product of "best professional judgment" is the existing hierarchical chain of review and approval that comprises the Agency decision-making process. Remediation, permit, compliance, and enforcement-related decisions are first proposed in draft form and then further reviewed, refined, and finalized by staff that is increasingly more knowledgeable and experienced. Some Agency decisions are then further reviewed by U.S. Environmental Protection Agency Region 5 (USEPA Region 5).

The formal chain of review and approval is in place throughout the Agency, for each separate environmental activity. It is one of the principle means by which determinations are made, decisions finalized, requisitions approved, and training needs assessed. The Agency uses a number of other quality system tools that are discussed in this Quality Management Plan to assure that all Agency decisions and work products are protective of public health and the environment, based on effective use of the best available data, and reflective of the best professional judgment of the Agency.

The internal chain of review also is used to review and approve some quality system documentation; particularly policies, SOPs, and QAPPs. These document types are reviewed and approved by the

Agency Quality Assurance (QA) Managers, as elaborated in the Agency Policy, Standard Operating Procedure (SOP), and Quality Assurance Project Plan (QAPP) Documentation Policy. The Policy, SOP, and QAPP Documentation Policy establishes development, review, and approval roles and requirements for policies, SOPs, and QAPPs, as well as schedules for keeping these document types up to date and accessible to all Agency staff.

The Structure of the IDEM Quality Management Plan

The Indiana Department of Environmental Management's (IDEM's) mission is to implement federal and state regulations to protect human health and the environment. The IDEM 2007 QMP provides an overview of the manner in which each of the USEPA-required elements, as outlined in "USEPA Requirements for Quality Management Plans, USEPA QA/R-2, (Reissued May 2006)" is addressed throughout the Agency. The branch QMPs address specific quality assurance/quality control (QA/QC) practices and methodologies.

Previous draft versions of the IDEM 2007 QMP used the USEPA -required elements as the sole organizing framework. A single chapter focused on each element, and all the information from the entire Agency that related to that element was included in that single chapter.

The IDEM 2007QMP reflects the Agency's organizational structure. It addresses those Quality Assurance (QA) issues that are organized, documented, planned, implemented, assessed, or improved in the same manner Agency-wide. It documents that which is common to all the branches. It is augmented by the various branch-level QMPs that address those QA-related issues specific to each respective branch. Similarly, as the IDEM 2007 QMP is organized to address each of ten (10) USEPA -required QA elements, the various IDEM branch QMPs each focus on only those USEPA -required QA elements that are applicable to QA activities within the branch, and not otherwise addressed by the Agency-wide QMP.

The resulting, two-tiered document allows more accurate descriptions of both Agency-wide practices and program area specific details. Any user or reviewer can assess the overall system or easily isolate more program area specific details Development of the IDEM QMP is the responsibility of the Agency QA Managers, using USEPA quality system guidance documents. The Agency QA Managers receive information, and comments from Agency Branch Chiefs (BCs), SOP/QAPP committee members, Agency staff, and executive staff during development or revision of the Agency QMP. Final revision of the IDEM QMP incorporates comments from the USEPA Region 5 and Great Lakes National Program Office (GLNPO) QA Managers.

IDEM branch QMPs are developed by Branch Chiefs or designees using a template developed by the Agency QA Managers. Review of branch QMPs is done by the Agency QA Managers, with additional input from Agency executive staff. Agency QA Managers ensure that each branch QMP addresses all the USEPA -required elements of the QMP identified by "USEPA Requirements for Quality Management Plans USEPA QA/R-2" not otherwise addressed in the IDEM 2007 QMP. Revisions of draft branch QMPs are based on Agency QA Managers and executive staff comments. Branch QMPs are finalized through the collaborative efforts of these parties.

1. Management and Organization

Purpose – To document the overall policy, scope, applicability, and management responsibilities of IDEM's quality system

1.1. Quality Assurance (QA) Policy

1.1.1. Importance of Quality Assurance (QA) System:

The Indiana Department of Environmental Management (IDEM) Quality Management Plan (QMP) serves as the organizing mechanism for the Agency quality system. It also serves as an inventory of various program and Agency-wide QA/QC documents and practices.

For external customers, the two tier structure of the IDEM QMP allows the document to function as a report on, or road map of, the Agency quality system. Within IDEM, the dual level QMP structure enables the Agency's organizational branches to use individualized branch QMPs as the driving force for consistent documentation and continual improvement.

The development and use of an effective quality system will have a positive impact on Agency efforts to meet IDEM's 2005-2007 EnPPA commitments.

The Agency-wide Quality Management Plan (QMP), the Agency "Policy, SOP, and QAPP Documentation Policy" (which replaces the Agency Project and Process Documentation Policy and the Administrative Documentation Policy), and all quality assurance (QA) related templates, checklists, training materials and other quality system documents listed under 2.1. Quality System Documentation are developed by the Agency QA Managers. Agency quality assurance (QA) documents are based on USEPA established requirements or guidance.

During development or revision, each of these Agency QA documents is circulated as appropriate among Agency executive staff, managers (Branch Chiefs and Section Chiefs), SOP/QAPP committee members (see 1.1.4. QA Resources, 1.4.1. Internal Coordination, and 1.5. Communications), and other interested staff for correction and comment. After comments are incorporated as appropriate, the document is circulated again for final review, revision, and signature.

The Agency QA Managers promote, coordinate, and manage the QA activities within the Agency. They work under the direction and supervision of the Agency executive staff while also serving in an advisory capacity to executive staff regarding QA issues. The Agency QA Managers are responsible for the development of the IDEM QMP and other Agency-wide QA policies, templates, tools, and training materials that may be developed in addition to USEPA Region 5 provided quality assurance training. Agency QA Managers both drive and track the development and improvement of the branch QMPs, as well as various Agency-wide and branch or section specific policies, SOPs, and QAPPs. (The responsibilities of Agency QA Managers, Branch Quality Assurance (QA) Coordinators, Section QA Contracts, and various levels of Agency management are listed in more detail in the table at 1.1.4. Quality Assurance (QA) Resources.)

USEPA requires that quality assurance managers of entities receiving federal funds or acting on behalf of USEPA have the capability of functioning across program areas, independently of the managerial hierarchy of those program areas. Although independent of the program areas, the approach to evaluation, corrective action, and continual improvement taken by the IDEM Agency QA Managers is team oriented. Agency QA Managers work with program area managers to build consensus, and if there are disagreements about recommendations from Agency QA Managers, dispute resolution is implemented through consensus or through staged implementation of Agency QA Managers recommendations by the existing management structure of Section Chiefs (SCs), Branch Chiefs (BCs), and Assistant Commissioners (ACs). The Agency QA Managers work with USEPA Region 5 and GLNPO QA Managers, and rely on them for ongoing comment and training.

1.1.2. Agency Policy, Standard Operating Procedure (SOP), and Quality Assurance Project Plan (QAPP) Documentation Policy:

The attached Agency Policy, SOP, and QAPP Documentation Policy (see Appendix A) establishes Quality Assurance (QA) related requirements for all authorized policies, standard operating procedures (SOPs), and quality assurance project plans (QAPPs) to ensure that Agency QA documents are consistent with Agency and USEPA Quality Assurance standards. It also clarifies staff QA roles; establishes applicability, development, content, use, maintenance, storage, and approval process requirements for all policies, SOPs, and QAPPs; and describes the management, and the electronic and hard copy storage and accessibility requirements for all Agency QA-related documents. Agency QA documents are stored in a QA library and in shared document storage folders in the Agency computer system.

1.1.3. Quality Assurance (QA) System Goals:

IDEM has implemented a cycle of continuing re-evaluation of its existing Quality Assurance/Quality Control (QA/QC) tools and methodologies. The Agency's emphasis on the continuous improvement of its quality system is a key component of its drive to provide stakeholders and the public with quick, efficient, predictable, fair and consistent implementation of federal and state regulations in a manner that protects human health and the environment.

The Agency has the following specific QA system goals:

Electronic QA document library – IDEM is establishing an electronic library to house Agency Policy, SOP, QAPP and QMP documents. Documents are arranged in alphabetical order by their document name in a spreadsheet that is viewable by Agency staff. Spreadsheet columns include information such as; Coverage Area, Policy or SOP Document Number, Effective Date, Review Cycle, Release Date, Office, Branch, Section and QA Contact. Staff may quickly access any quality system document by clicking document name, viewing its entire contents and printing it if need be. Centralizing quality assurance (QA) documents will ensure that all Agency staff is working from the same documents."

Paper copy QA document library – In conjunction with the electronic QA document library, Agency QA Managers also maintain a hard copy collection of all authorized Agency QA documents (QMPs, policies, SOPs, and QAPPs) with original signatures. This will serve both as a confirmation of the accuracy of the electronic QA library, and as a means of ensuring document version control.

Institute Quality Assurance Project Plan (QAPP) development and assessment procedures – The Agency QA Managers coordinate with sections or program areas developing QAPPs to ensure they receive QA support during QAPP development. Following evaluation and incorporation of comments, Agency QA Managers will sign QAPPs to signify that they participated in the review of QAPPs during development.

Identify primary and secondary data use - In response to the 2005 USEPA Region 5 Management Systems Review (MSR) findings, the Agency now inventories environmental activities/programs that use 1) primary data (data collected by the Agency), and/or 2) secondary data (data collected by a non-Agency source) to support decision-making.

Internal QA assessment – In response to the 2005 USEPA Region 5 MSR, the Agency QA Managers inventoried and assessed the Agency QA system. The inventory, conducted through development of branch QMPs, will detail branch Standard Operating Procedures/Quality Assurance Project Plan (SOP/QAPP) usage and will identify gaps in the documentation of projects using QAPPs. The inventory will also assess levels of QA support and the use of the Data Quality Objective (DQO) process and other systematic planning processes for project planning.

Develop ten (10) SOPs per section by July, 2007 - Now that more than 42% of Agency staff has attended SOP/Policy development training, many Section Chiefs and Section QA

Contacts will be working together with their staff to determine what SOPs and written policies that need to be developed or those that need to be updated. Each section developed a prioritized list of SOPs and policies to work on. Periodically, the Agency QA Managers request an updated SOP/Policy priority list from section staff as an informal means of gauging Agency progress in developing SOPs and policies.

Promote the permanent ongoing development and refinement of SOPs and written policies - The Agency will continue to document policies and procedures and the Agency QA Managers will maintain these documents. This commitment will be a permanent part of the Agency workload, and it will ensure all Agency decisions will be made in a speedy, predictable, and transparent manner.

1.1.4. Quality Assurance (QA) Resources:

IDEM is committing approximately 64.92 FTE (full time equivalent) to 72.42 FTE staff for maintenance and improvement of the Agency quality system, and to implementation of ongoing QA/QC review of environmental data and QAPPs.

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
Agency Quality Assurance Managers	Agency-wide, operating in the Office of External Affairs, Planning and Assessment	2.0 FTE (full time equivalent) 2 staff that work full time on QA issues	Shall: A. Coordinate and manage quality assurance activities within the Agency. B. Function across program areas, independent of program area managerial hierarchy. C. Ensure Agency offices, branches, and sections follow proper quality assurance/quality control (QA/QC) procedures. D. Develop and maintain the Agency's USEPA -required Quality Management Plan and its components. E. Promote and track the development and completion of policies, SOPs, and QAPPs by Agency ACs, BCs, SCs, and staff. F. Review policies, SOPs, and QAPPs for appropriate formatting before they are finalized. G. Assign a document ID number to each policy, SOP, or QAPP developed or revised within the Agency. H. Catalog, organize, and store electronic and signed paper copies of approved Agency, office, branch, and section level policies, SOPs, and QAPPs in a location accessible to all Agency staff. I. Properly archive all Agency policies, SOPs, and QAPPs no longer in effect. J. Develop quality system-related policies, templates, checklists,

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
			training materials, and other guidance to assist Agency ACs, BCs, SCs, and staff with developing effective policies, SOPs, and QAPPS using a standardized Agency format. K. Train Agency staff on the development of policies, SOPs, QAPPs, and other quality system-related documents and associated flow charts. L. Determine if documents meet Agency requirements for form and content and if so, sign the documents to signify that they have met those requirements. M. Review and approve branch-level QMPs.
IDEM SOP/QAPP Committee	Includes representatives from various program branches within the Agency	0.5 FTE 10 staff from various branches each contributing 5% of FTE each	Shall: A. Be comprised of staff selected by Agency management that represent the various Agency program areas, branch QA coordinators, or involved staff. B. Attend periodic committee meetings (generally held monthly for one hour). C. Provide guidance and feedback on Agency quality assurance initiatives.
Branch Quality Assurance (QA) Coordinators	Each Agency branch has a QA coordinator	0.75 to 1.5 FTE 15 staff, each contributing approximately 5% to 10% of work time to QA issues	Shall: A. Be designated by the Branch Chief to assist with quality-related activities. B. Serve as the liaison between the Agency QA Manager(s), the SOP committee, the Branch Chief, Section QA contacts, and Branch staff regarding the development of policies, SOPs, and QAPPs. C. Assist the Branch Chief and staff as requested, by developing, reviewing, and/or commenting on draft policies, SOPs, and (when applicable) QAPPs. D. Attend Agency SOP/policy development-related training. E. Assist branch staff to understand Agency QA related requirements and how to use the forms, templates, and tools associated with the development and implementation of policies,

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
			SOPs, and QAPPs. F. Solicit comments from Regional Office directors and staff regarding draft policies, SOPs, and QAPPs under development by the branch that have the potential to affect regional office operations.
Section QA Contacts	Each Agency branch is comprised of several sections, and each section has as QA contact	3.0 to 6.0 FTE Approximately 60 staff, each contributing 5%-10% of work time to QA issues	Shall: A. Be designated by the Branch Chief to assist with quality-related activities. B. Serve as the liaison between the Agency QA Manager(s), the SOP committee, the Branch Chief, Section QA contacts, and Branch staff regarding the development of policies, SOPs, and QAPPs. C. Assist the Branch Chief and staff as requested, by developing, reviewing, and/or commenting on draft policies, SOPs, and (when applicable) QAPPs. D. Attend Agency SOP/policy development-related training. E. Assist branch staff to understand Agency QA related requirements and how to use the forms, templates, and tools associated with the development and implementation of policies, SOPs, and QAPPs. F. Solicit comments from Regional Office directors and staff regarding draft policies, SOPs, and QAPPs under development by the branch that have the potential to affect regional office operations.
Various program staff	Various staff from throughout the Agency	Approximately 5.0 FTE Approximately 100 staff at 5% each working on SOP development at any given moment. More than 1,000 man-hours of Agency-wide	A. Staff assigned to develop SOPs for use within their specific area of activity; attend a three (3) hour SOP/Policy/Flowchart development class. (Approximately two-thirds -- 218 of 331, as of 7/20/06 -- of staff taking SOP training were neither managers nor QA staff) B. Participate in the development of QA-related documents as assigned.

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
		SOP training have been provided to managers and staff (through 8/23/06).	
IDEM Regional Office Staff	49 Regional Office (RO) staff representing air, land and water programs, as well as, the Office of Pollution Prevention and Technical Assistance	0.98 FTE The 49 RO staff received a combined total of 75 man-hours in SOP training, and each contributing 2% of time to QA.	Shall: A. Participate in training courses provided at the Regional Offices B. Review and comment on policies and SOPs when presented with the opportunity. C. Follow approved Agency policies and SOPs.
Commissioner		0.05 FTE	A. Have final approval of all Agency policies, Standard Operating Procedures (SOPs), and Quality Assurance Project Plans (QAPPs).
Assistant Commissioner, External Affairs	Office of External Affairs	0.05 FTE	A. Provide crucial Agency executive staff endorsement, support, and authorization; ensure QA-related workload is addressed; B. Review, approve, and sign quality-related documents
Director, Planning and Assessment	Office of External Affairs	0.20 FTE	Supervise Agency QA Managers; participate in coordination meetings; and provide supervisory level support
Assistant Commissioners and Deputy Assistant Commissioners	Office of Air Quality Office of Land Quality Office of Water Quality Office of Compliance and Enforcement Office of Pollution Prevention and Technical Assistance Office of Legal Counsel (See Organization Chart, Appendix C)	0.40 FTE each contributing approximately 5% of work time to QA issues	A. Manage the development and use of policies, Standard Operating Procedures (SOPs), and when applicable, Quality Assurance Project Plans within their respective office program area. B. Ensure that branches and sections within the respective office are developing policies, SOPs, and QAPPs. C. Designate which staff shall review and sign policies, SOPs, or QAPPs developed and/or used within their respective office program area. D. Ensure that an electronic copy of each policy, SOP, and QAPP developed within their respective

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
			program areas be submitted to the Agency QA Managers for format review, comment, and assignment of a document identification (ID) number, before the office-approved, signed paper copy of the document is submitted to the Agency QA Managers for final signature, and storage in the Agency quality assurance library. E. Ensure that all policies, SOPs, and QAPPs used within their respective office program areas are periodically updated. F. Notify the Agency QA Managers when a policy, SOP, or QAPP is no longer in effect so it may be properly archived. G. Maintain compliance with IC 13-14-1-11.5 "Duties of Department: policy statements," by ensuring that all draft non-rule policies are made available for public inspection and comment, and brought before the appropriate board(s) prior to being put into effect. All effective non-rule policies shall be accessible to the regulated community and the public. H. Determine, in conjunction with the respective Branch Chief (BC), the science staff that will review a Quality Assurance Project Plan (QAPP).
Branch Chief	Each Branch of IDEM	0.75 to 1.5 FTE each contributing approximately 5% to 10% of work time to QA issues	A. Manage the development and use of policies, Standard Operating Procedures (SOPs), and when applicable, Quality Assurance Project Plans (QAPPs) throughout the branch. B. Ensure that all branch staff has access to, knowledge of, and complies with all Agency policies and all applicable branch and section level policies, SOPs, and QAPPs. C. Review and authorize by signature policies, SOPs, and QAPPs developed by the branch and subordinate sections. D. Designate the Branch Quality Assurance Coordinator and other

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
			staff who shall review and approve by signature branch SOPs, and QAPPs. E. Ensure that an electronic copy of each policy, SOP, or QAPP developed within the branch be submitted to the Agency Quality Assurance (QA) Managers for format review, comment, and assignment of a document ID number before the branch-approved, signed paper copy of the document is submitted to the Agency QA Managers for final signature and storage in the Agency quality assurance library. F. Work with the AC and SCs to ensure all policies, SOPs, and QAPPs used within the branch are updated as required by 6.4 (below). G. Develop and maintain any additional guidance necessary for the implementation of a policy, SOP, or QAPP. H. Notify the Agency QA Managers when a policy, SOP, or QAPP is no longer in effect so that it may be properly archived. I. Determine, in conjunction with the respective Assistance Commissioner (AC), the science staff that will review a Quality Assurance Project Plan (QAPP).
Section Chief	Each Section of IDEM (approx. 60 sections)	3.0 to 6.0 FTE each contributing approximately 5% to 10% of work time to QA issues	A. Manage the development of policies, SOPs, and QAPPs within the section. B. Bring potential quality assurance concerns to the attention of the appropriate AC or BC. C. Ensure that all section staff has access to, knowledge of, and complies with all Agency policies and all applicable branch and section level policies, SOPs, and QAPPs. D. Review and approve by signature any policies, SOPs, or QAPPs developed by the sections, or at the branch level as requested by the Branch Chief. E. Designate the section quality assurance (QA) contact and other

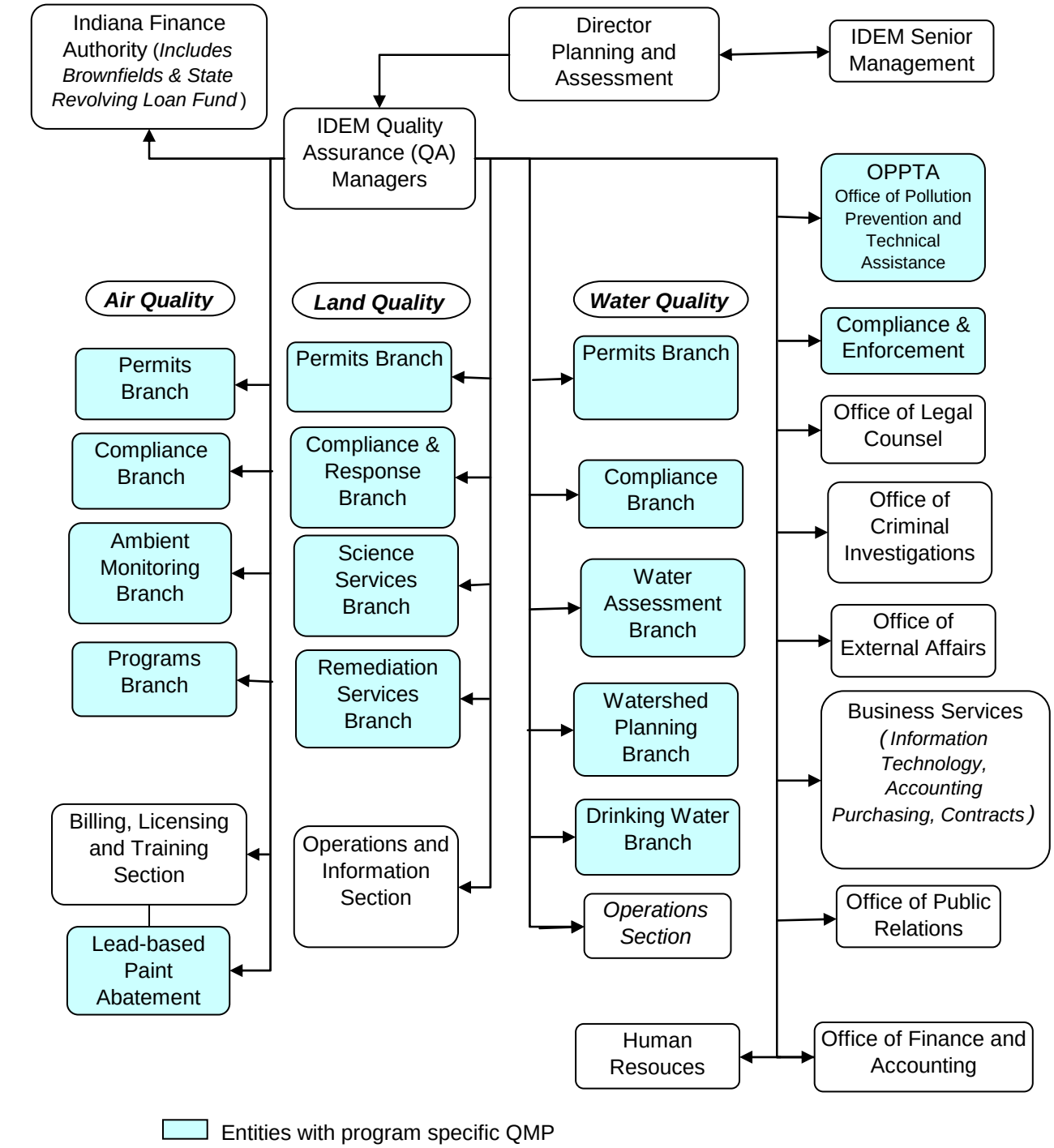
Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
			staff who shall review and sign policies, SOPs, or QAPPs developed and/or used within the section. F. Ensure that an electronic copy of each policy, SOP, or QAPP developed within the section be submitted to the Agency QA Managers for format review, comment, and assignment of a document ID number, before the section-approved, signed paper copy of the document is submitted to the Agency QA Managers for final signature and storage in the Agency QA library. G. Work with the AC and BCs to ensure all policies, SOPs, and QAPPs used within the section are updated as required by 6.4 (below). H. Develop and maintain any additional guidance necessary for the implementation of a policy, SOP, or QAPP. I. Notify the Agency QA Managers when a policy, SOP, or QAPP is no longer in effect so that it may be properly archived.
Regional Office Director	Each Regional Office of IDEM	0.06 FTE Each contributing approximately 2% of time to QA issues	A. Ensure that all regional office staff has access to, knowledge of, and comply with all Agency policies, and applicable branch and section level policies, SOPs, and QAPPs. B. Bring potential quality assurance concerns to the attention of the appropriate AC or BC. C. Coordinate with the Offices of Air, Land, and Water Quality to participate in office, branch, or section level development of policies, SOPs, or QAPPs that could affect Region Office operations.
Project Manager	Approximately 35 project managers in OLQ each contributing approximately 20% of work time to QA issues OAQ does not conduct site specific projects,	7.0 FTE	A. Develop or review Quality Assurance Project Plans (QAPPs) (but not both activities for the same QAPP). B. Ensure that a QAPP is fully developed and approved before work commences. C. Ensure that any changes to

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
	except as incorporated into its monitoring programs, for which the FTE is included under the Ambient Air Monitoring Branch PTE below OWQ project managers provide tech support only, any QA FTE already is included with OWQ Watershed FTE		the QAPP are documented and approved, before work continues. D. Implement the QAPP to its conclusion, ensuring that project activities are performed as required. E. Complete or designate staff to complete, the duties of the Project Manager listed in the Agency Grants Management Policy. F. Ensure, if the project and associated QAPP involve federal grant funds, that the Grant Coordinator of the respective office is kept informed of the status of QAPP development, approval, or completion, or of any modifications to the QAPP that could impact grant timetables, deliverables, or funding levels. G. Ensure that any project contractors or sub-grant recipients understand the contract agreement to meet project goals, schedules, or revisions. H. Participate in USEPA Region 5 provided training for: 1. Introduction to QA Project Plans. 2. Introduction to Data Quality Objectives. I. Notify Agency QA Managers of all ongoing and new QAPP agreements with USEPA Region 5 program counterparts.
Science and Data Support Staff	OLQ Science Services 19 chemists that do 20% QA , 9 data specialist that do about 50% QA, and 1 GIS staff that does 10% QA =8.4 FTE OAQ Ambient Air Monitoring, QA Section 7 staff do about 90% QA, remainder of Ambient Air branch 20 staff doing approximately 5% QA = 7.3 FTE OWQ Water Assessment Biological Studies, Surveys, and Env. Tox &	30.58	Reviewing numerical or scientific data, or QAPPs

Activity	Branch	QA Staff Resources	QA Role & Tools or Standards Used
	Chem 3.5 =8.5 FTE OAQ Programs = 1.6 FTE OWQ Watershed =1.38 FTE Drinking water =3.0 FTE OAQ Compliance =7.2 OWQ Compliance =3.5 OLQ Compliance (included in sciences services, above)		
Program Grants Coordinator	Each Office of IDEM	0.3 FTE 6 doing 5% QA work each	A. Notify the Agency grant director of any change to the QAPP that could impact grant timetables, deliverables, or funding levels. B. Coordinate the development of grant QAPP reports. C. Act as a liaison between the Agency accounting office and Agency programs.

1.2. Quality System Organizational Chart

IDEM Quality Assurance System Organizational Chart



1.3. QA Staff Positions and Roles

Name/Title	Branch	Role
Commissioner		
Assistant Commissioner	Office of External Affairs	Provide executive staff support for improvements to the Agency quality management system
Director, Planning and Assessment	Office of External Affairs	Provide review and comment on materials developed by Quality Assurance managers; help facilitate and coordinate with other Agency staff regarding improving the Agency quality system
Agency Quality Assurance Managers	IDEM Quality Management Team	See roles in 1.1.4.
Office of Air Quality		
Assistant Commissioner	Office of Air Quality (OAQ)	Provide OAQ executive staff support to QA-related efforts
Branch Quality Assurance (QA) Coordinator	Permit Branch	See roles in 1.1.4.
Branch QA Coordinator	Compliance Branch	
Branch QA Coordinator	Ambient Monitoring Branch	
Branch QA Coordinator	Programs Branch	
Section QA Contact	Billing, Licensing and Training Section	Fills the dual roles of branch QA coordinator and section QA contact described in 1.1.4.; "Orphaned" section, not part of any specific OAQ branch.
Office of Land Quality		
Assistant Commissioner	Office of Land Quality	Provide OLQ executive staff support to QA-related efforts
Branch QA Coordinator	Permit Branch	OLQ Branch QA Coordinators See roles in 1.1.4.
Branch QA Coordinator	Compliance & Response Branch	
Branch QA Coordinator	Science Services Branch	
Branch QA Coordinator	Remediation Services Branch	
Section QA Contact	Operations & Information Section	Fills the dual roles of branch QA coordinator and section QA contact described in 1.1.3.; "Orphaned" section, not part of any specific OAQ branch.
Office of Water Quality		
Assistant Commissioner	Office of Water Quality	Provide OWQ executive staff support to QA-related efforts
Branch Quality Assurance (QA) Coordinator	Permit Branch	See roles in 1.1.4.
Branch QA Coordinator	Compliance Branch	
Branch QA Coordinator	Assessment Branch	
Branch QA Coordinator	Watershed Planning Branch	
Branch QA Coordinator	Drinking Water Branch	
Section QA Contact	Operations Section	Fills the dual roles of branch QA

Name/Title	Branch	Role
		coordinator and section QA contact described in 1.1.3.; "Orphaned" section, not part of any specific OAQ branch.
Office of Pollution Prevention and Technical Assistance		
Branch QA Coordinator	Office of Pollution Prevention & Technical Assistance	See roles in 1.1.4.
Office of Compliance and Enforcement		
Section QA Contacts		See roles in 1.1.4.
Office of Legal Counsel		
Section QA Contacts		See roles in 1.1.4.
Office of Criminal Investigations		
Section QA Contacts		See roles in 1.1.4.
Indiana Finance Authority		
Section QA Contact	Brownfields	See roles in 1.1.4.
Section QA Contact	State Revolving Loan Fund (drinking water/wastewater)	
Office of External Affairs		
Section QA Contacts Branch QA Coordinator	Business Services Information Technology	See roles in 1.1.4.
Branch QA Coordinator	Finance & Accounting	See roles in 1.1.4.
Section QA Contact	Media and Communications Services	See roles in 1.1.4.
Section QA Contact	Office of Public Relations: Community Relations	See roles in 1.1.4.
Section QA Contact	Contract Services	See roles in 1.1.4.
Section QA Contact	Human Resources	See roles in 1.1.4.

1.4. Programs Covered by QA System

1.4.1. Technical Programs Subject to QA/QC Processes:

IDEM defines a "technical program" as "a process, or collection of related processes, that involve the collection or analysis of quantitative data and result in an Agency decision." Many Agency environmental activities can be categorized as "technical programs". Nearly all Agency activities are included in the quality system.

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, documentation, assessment, reporting and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client. QA activities improve the work product by focusing on improving the work process. QA activities are applicable to both technical and administrative programs, and as a result, nearly all Agency activities are subject to quality assurance activity and scrutiny. This is manifested in the expanded development and use of Standard Operating Procedures (SOPs) and written policies by each level and (program) area of environmental activity throughout the Agency.

Quality Control (QC) is a system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet

the stated requirements. QC activities evaluate the quality of the work product to ensure that the process is performing as expected or required by verifying that the work product is a usable quality product. QC verification should be non-subjective since it requires comparing the work product to a standard.

Whenever appropriate, the Agency incorporates the USEPA's seven (7) step Systematic Planning Process (SPP; found in USEPA QA/G-4 Guidance on Systematic Planning: Using the Data Quality Objectives Process, February 2006) to plan data gathering and data analysis activities. Quality Assurance Project Plans are used for data gathering activities, use of secondary data for environmental decision-making, and for planning site specific projects.

Where Agency work products subjected to the QC process were developed as part of the QAPP process, the evaluation can rely on data verification. Similarly, some process that may not follow the QAPP format may still involve the use of systematic planning and could rely on data verification. However, the more an Agency work product is based on the collective "best professional judgment" of Agency staff (as described above in the QMP introduction), the more the QC process must rely on the assessment of the Agency chain of review and approval, rather than non-subjective data verification, as the principle quality control component.

In summary, nearly all activities associated with the conduct of the Agency's mission involve processes that are being reviewed and improved through the quality assurance process. Agency processes also are subject to some type of quality control measures. While data verification and validation may be the most appropriate QC tool for evaluating some work products, the Agency's chain of review is the more appropriate QC tool for assessing other work products. Some Agency work products may be subjected to both data validation and hierarchical review.

The primary activities (permitting, compliance, enforcement and remediation) in each of the various media program areas (air, land and water) associated with the implementation of Agency's mission are more likely to involve some subjective interpretation of data, statute or rule. Agency programs that provide scientific support to these core activities are most likely to depend on data verification as their principle QC tool. Those program areas are Ambient Air Monitoring, Water Assessment, Land Science Services; and Watershed Planning, and Land Remediation Services.

1.4.2. Internal Coordination:

Agency QA activities are coordinated internally by the Agency QA Managers, working with Agency Branch Chiefs, Branch QA Coordinators, Section Chiefs, Section QA Contacts, project managers, SOP/QAPP committee members, and Agency staff.

1.4.3. Oversight of Contractors and External Organizations:

The Agency has several tools to ensure the control of any work contracted by the Agency or any branch of the Agency:

- The Professional Service Contract Policy, A-013-OEA-07-P-R1, May 1, 2006, requires that contractors abide by all Agency policies and standard operating procedures.
- The boilerplate language used in all IDEM professional/personal services contracts (see sections 27 and 36, page 61-64 of http://www2.idoa.state.in.us/proc/rfp_manual_070106.doc) requires that contractors and their employees and subcontractors comply with all applicable licensing standards, certification standards, accrediting standards and any other laws, rules or regulations governing their services. Contractors must submit written progress reports to the Agency assuring that work is progressing on schedule and in accordance with contract requirements.
- The IDEM Memorandum Of Understanding (MOU) and Memorandum of Agreement (MOA) Policy, A-027-OEA-06-P-R0, August 25, 2006, MOUs and MOAs in which

there is a financial obligation, require a standard contract consistent with the IDEM Professional Service Contract Policy and routed through the proper contract signatory process.

- The Agency Grants Management Policy, A-018-OEA-06-P-R1, March I, 2007, requires that all grants or sub-grants awarded by IDEM be treated as a contractual arrangement.

Only some Agency environmental and technical activities contract out work. Any work contracted out at the branch level is discussed in the respective branch-level QMP. As addressed in the Agency-wide portion of the Agency QMP, only some computer services and some training services are contracted out.

Computer services are contracted out to the Indiana Office of Technology (IOT). IDEM Information Technology project managers, software developers and business consultants each play roles in managing the various contractual agreements the Agency has with IOT to ensure that QA/QC issues are addressed. These roles are discussed in Part 6 of this document.

Hazardous Waste Operations and Emergency Response (HAZWOPER) training, which is required, as specified in Health and Safety Training Policy, A-030-OEA-07-P-R1, January 1, 2007, of staff from various Agency programs, is carried out under a contract that is monitored by the Agency Health & Safety Director. The Health & Safety Director coordinates the training, which is attended by various Agency staff. Training topics are developed based on the input from programs with Agency staff that do field work. (see 3.1.). The Health & Safety Director, who sits in on many of the classes, works closely with the training contractor to ensure that all American National Standards Institute (ANSI) training recommendations are followed and that all training topics relevant to the safety of Agency staff that do field work are met. Details of the training are addressed in Part 3 of this document.

1.5. Communication

The Agency QA Managers communicate QA/QC-related requirements and activities to program staff through the following channels:

Agency-wide email distribution - Announcement of QA-related news or roll out of new policies is made through Agency-wide email, distributed by the Assistant Commissioner of External Affairs.

Posting on the Agency-wide electronic SharePoint site – Agency staff may access all QA policies and SOPs through SharePoint.

The SOP/QAPP Committee – This committee is comprised of staff representing various Agency program offices. Committee members play a crucial advisory role in the Agency initiative to improve consistency, efficiency, and speed through the development of SOPs, QAPPs, and other quality system tools. The committee reviews and provides comments on all new policies and QA tools, assesses staff QA workload, communicates QA-related information to staff, and provides a forum for issue resolution.

Branch QA coordinators – Each of IDEM's organizational branches has designated a Branch QA Coordinator, who is primarily responsible for leading branch SOP development and maintenance activities. The Agency QA Managers direct branch-specific QA communications to branch QA coordinators for dissemination to branch management and staff.

Section QA contacts – Each of IDEM's sections has designated a Section QA Contact, who is primarily responsible for leading SOP development and maintenance activities within the section. The Agency QA Managers direct section-specific QA communications to Section QA Contacts for dissemination to section management and staff.

2. Quality System Components

Purpose – To document how IDEM manages its quality system and defines the primary responsibilities for managing and implementing each component of the system

2.1. Quality System Description

2.1.1. Documentation:

Listed below is the IDEM Agency-wide Quality Assurance/Quality Control documentation used by program area branches, sections or environmental activities. Quality system documents used on a branch-specific basis only, are listed within the various branch-level "sub" Quality Management Plans.

Name of QA Document	Description	Type	Effective Date	Name of Section to which it applies	Name of Environmental Activity to which it applies
USEPA QA/QC Documents Applicable to the IDEM Quality System Agency-Wide					
Requirements for Quality Management Plans (QA/R-2)	R-2 Establishes Quality Management Plan (QMP) requirements	Policy	May 2006	Applies to entire Agency quality system	Applies to the entire Agency quality plan and to all branches and sections
Guidance for Preparation of Standard Operating Procedures (SOPs)(QA/G-6)	G-6 Establishes content requirements for SOPs	Guidance	March 2001	Applies to entire Agency quality system	Applies to all environmental activities and support activities
USEPA QA/QC Documents Required for QAPP Preparation (Not all IDEM branches use QAPPs)					
USEPA Requirements for Quality Assurance Project Plans USEPA QA/R-5	R-5 Establishes content requirements for QAPPs	Policy	May 2006	Applies only to those Agency branches developing and using QAPPs	Applies only to environmental activities that gather and/or analyze data
Guidance for Quality Assurance Project Plans (QAPPs) (QA/G-5)	G-5 Provides guidance on QAPP development	Guidance	December 2002	Applies only to those Agency branches developing and using QAPPs	Applies only to environmental activities that gather and/or analyze data
Guidance on Systematic Planning Using the Data Quality Objectives Process USEPA QA/G-4	G4- Provides guidance on using the seven-step Systematic Planning Process (SPP) for determining the type, quantity and quality of data needed to reach a defensible decision	Guidance	February 2006	Applies only to those Agency branches developing and using QAPPs	Applies only to environmental activities that gather and/or analyze data
QA/QC Documents Developed and Used by IDEM					

Name of QA Document	Description	Type	Effective Date	Name of Section to which it applies	Name of Environmental Activity to which it applies
Policy, Standard Operating Procedure (SOP), and Quality Assurance Project Plan (QAPP), and Policy Documentation Policy, or Policy, SOP, and QAPP Documentation Policy (See Appendix A)	Agency policy that ensures compliance with USEPA Order 5360.1. It establishes requirements for QA document applicability, development, content, use, maintenance, and storage (by the Agency QA Managers) and sets approval process requirements for all Agency policies, SOPs, and QAPPs	Policy	February 15 , 2007	Applies to all Agency program areas and offices	All core Agency activities, as well as all support activities
QAPP Development and Approval SOP(See Appendix A)	Details Quality Assurance Project Plan (QAPP) development and review procedures; Assist Agency project and designated grant managers in assessing which operations require the development of a QAPP; and guides project/designated grant managers through the QAPP development and approval process.	SOP	June 5, 2006	Applies to Agency staff that author or review QAPPs; primarily the science sections (Air Monitoring, Water Assessment, and Land Science Services) and associated remediation projects	Applies to all program areas that gather, generate or use verifiable data
Policy Template (See Appendix B)	Provides format for purpose, scope, summary, definitions, roles, policy statement, references, and signature	Template	February 15 , 2007	Applies to all policy development and approval processes for all Agency program areas and offices	All core Agency activities, as well as all support activities
SOP Template (See Appendix B)	Provides format for title, purpose, version #, overview work flow chart, definitions, roles, description of equipment, forms, and/or software, procedural flowchart, written procedure, standards and checklists, records management,	Template	February 15 , 2007	Applies to all Agency procedures and projects requiring SOPs or QAPPs	All core Agency activities, as well as all support activities

Name of QA Document	Description	Type	Effective Date	Name of Section to which it applies	Name of Environmental Activity to which it applies
	QA/QC measures, continuous improvement cycle, references, history of revisions, and appendix				
QAPP Template (See Appendix B)	Format includes the 24 USEPA -required QAPP elements from USEPA QA/R-5, as organized under; project development, data generation and acquisition, assessment and oversight, data validation and usability	Template	February 15 , 2007	Applies primarily to the science sections (Air Monitoring, Water Assessment, and Land Science Services) and associated remediation projects	All gathering, analysis or use of verifiable environmental data
Policy Checklist	Checklist ensuring complete development of an Agency policy	Checklist	November 1, 2005	Anyone developing a policy	Policy development
SOP Checklist	Checklist ensuring complete development of a SOP	Checklist	January 23, 2006	Anyone developing a SOP	SOP development
QAPP Review Checklist	Checklist ensuring complete development of a QAPP	Checklist	June 5, 2006	Anyone developing a QAPP	QAPP development
SOP Training Modules	1. Quality system overview 2. Writing SOPs 3. Developing flowcharts 4. Writing policies	Training Material	March 8. 2006	Necessary for any Agency staff who will be documenting polices, processes or project activities	All Agency environmental or support activities for which quality system documentation has value using a graded approach
The IDEM SOP Initiative: What Does It Mean For Managers?	Brief overview of the Agency SOP and quality system initiative and its impact on managers	Training Material	December 2005	All Agency Branch Chiefs (BCs), and Section Chiefs (SCs)	All Agency environmental or support activities
Standardization: Bringing SOPs to the IDEM Workplace	Detailed overview of the Agency SOP and quality system initiative	Training Material/ Guidance	November 2005	All Agency managers and staff	All Agency environmental or support activities
Contracts Policy,	Establishes guidelines for Professional Service	Policy	January 1, 2007	All procurement	All purchases more than

Name of QA Document	Description	Type	Effective Date	Name of Section to which it applies	Name of Environmental Activity to which it applies
Professional Service Contract Policy, A-013-OEA-07-P-R1, (See Appendix D)	Contracts initiated by IDEM				$2500
Grants Management Policy, A-018-OEA-07-P-R1, (See Appendix D)	Establishes guidelines and defines responsibilities for the management of grants received by IDEM.	Policy	March 1, 2007	All federal grant activities	All grant activities
Public Records Request Policy, A-017-OEA-06-P-R1, April 1, 2006 (See Appendix D)	Establishes responsibilities associated with the inspection and associated charges for the replication of Agency public records in compliance with IC 5-14-3 Indiana Access to Public Records Act and IC 13-14-11, and to ensure the integrity and completeness of Agency public records.	Policy	April 1, 2006	All Agency managers and staff	Agency Documents subject to Indiana Commission on Public Records (ICPR) Retention Schedules approval
E-mail Management Policy, A-002-OLC-07-P-R1, February, 1, 2007 (See Appendix D)	Establishes requirements for Agency staff to manage email and to identify and storage “retainable records” consistent with Indiana Commission on Public Records approved document retention schedules.	Policy	June 6, 2005, then February 1, 2007	All Agency staff	All Agency activities

2.1.2. Planning and Annual Review:

Agency Quality Assurance (QA) Managers, supported by Agency executive staff, are continually reviewing and assessing the tools and components of the IDEM quality system.

2.1.3. Management Assessments:

Because Agency QA Managers report regularly to Agency executive staff regarding the development and ongoing implementation of the Agency quality system, executive staff are regularly assessing the progress and implementation of the Agency quality system and providing support and direction for ongoing improvement and identifying additional quality system needs.

2.1.4. Quality System Training:

Agency executive staff is committed to the development of a quality system, and use of quality system tools. The Agency has adopted a two-pronged approach to training Agency staff and encouraging the development of a more robust quality system.

At the “macro”, or Agency-wide level, the Quality Assurance managers and executive staff have used an assortment of USEPA -produced QA requirement documents and quality systems-related literature to tutor themselves on how to inventory and further build upon the IDEM quality system. Augmented by consultation with and comments from USEPA Region 5 and GLNPO QA Managers, this self-taught/learn-from-experience approach has enabled Agency Quality Assurance (QA) Managers and executive staff to develop the templates and expertise needed to revise the IDEM Agency-wide QMP, have assisted Branch Chiefs and their designees in drafting branch-level QMPs. This “macro-level” training has been a time-consuming process built on reading and analysis. Numerous one-on-one discussions among Agency QA Managers, executive staff and program area managers have occurred in conjunction with the drafting of branch-level QMPs.

At the “micro”, or activity-specific level of the Agency, staff have workload commitments and deadlines associated with the daily-decision-making activities of the Agency, in the form of permits, licenses, inspection reports, compliance assistance, remediation activities, and enforcement orders, quality system-related trainings have been more concise and to the point. To meet this need, Agency QA Managers developed a comprehensive training course that was presented approximately one third (1/3) of Agency program staff, during more than a dozen three (3) hour sessions. The training explained to staff how and why the IDEM QMP was being revised. It also provided them with all the information necessary to return to their work areas and develop activity-specific quality system documents: standard operating procedures (SOPs), policies, guidances, and process flowcharts that they could put to immediate use in their daily work.

Approximately 42% of all Agency staff has participated in the three (3) hour training listed in the table in 2.1.1. SOP Training Modules. The training is based on the twin principles that staff that does the work is best suited to document how the work is done; and the staff that developed the SOPs has a greater sense of ownership in the components of the quality system. The SOP training includes:

1. Quality System Overview - To explain in summary fashion why IDEM is documenting work processes in a standardized manner; how SOPs are part of a broader picture of Agency QA system; and how the development and use of SOPs, policies and the Agency and branch-level QMPs improves overall Agency efficiency, effectiveness and stakeholder satisfaction;

2. Writing SOPs – To explain how an SOP differs from a policy; how to segment a complex process; identify which segments of the more complex process can be isolated and documented as individual SOPs; what content needs to be included in an SOP; how to complete the Agency SOP template; and what is an efficient strategy for identifying and prioritizing processes needing SOPs;

3. Developing Flowcharts – To explain the difference between overview and process flowcharts; the advantages of flowcharts in lieu of text; how to use flowcharting software shapes and connectors to build standardized flowcharts; and how to insert flowcharts into a text document; and

4. Writing Policies – To explain how policies differ from SOPs; differences between policy types (administrative or interpretive of rules and statutes); and how to complete the Agency policy template.

The SOPs and policies that are being revised and produced as a result of this training each contain all the required components. They also capture a wide range of institutional knowledge, documenting it for use in promoting a consistent work product, for training new staff, or for evaluating work processes to see where additional improvements might be made. The many SOPs that have been and will be developed as a result of the SOP-policy training will serve as the building blocks for further developing the Agency quality system.

The use of this micro-level “development of building blocks” approach allows staff at the environmental activity level to attend a training session and then immediately use what they

have learned to develop tools that can assist them in their daily work. They can see the immediate "value-added" benefits of quality system documentation. In turn, staff may learn to view SOPs -- which are among the "micro units" of the quality system -- as components of a broader "macro" quality system. In IDEM's case, that is a branch-level Quality Management Plan that is, in turn, a component of the larger Agency- wide QMP.

This approach allows the Agency to move forward with any additional quality system training on an "as needed", or "as ready for it" basis that ensures staff are adequately trained prior to each new step in the development of the Agency quality system. Training is targeted to individuals based on their role in the quality system.

Using the graded approach to implement the Agency training program, those staff with more defined roles in the quality system may receive more training than those individuals with a lesser role in developing the quality system. Greatest emphasis is always placed on training that will bring the most immediate, value added to each group and each specific environmental activity. More staff benefit from SOPs and written policies, so more emphasis is placed on writing and using SOPs and policies. Fewer staff may need training in QAPPs, quality assessments, or other quality system components and processes.

2.1.5. Project-specific Quality Documentation:

Each of the three core media program areas; air, land, and water, has science support staff that operate using Operations Manuals/Program QAPPs. Most of the project-specific projects carried out by the Agency are for remediation projects conducted by the Office of Land Quality's Remediation Services Branch. Air Ambient Monitoring, Land Science Services, and Water Assessment also operate using quality documents, in cooperation with their program counterparts at USEPA Region 5.

2.2. Quality System Tools

Agency quality system tools include the following:

2.2.1. Quality Management Plans (quality system documentation):

Branch-level QMPs that address branch-specific quality practices and the IDEM Agency-wide QMP that addresses only Agency-wide quality issues and practices

2.2.2. Quality Systems Audits (management assessments) conducted by IDEM Quality Assurance managers (or by USEPA Region 5) and reported to the Agency executive staff:

Agency QA Managers will conduct a quality system audit of each Agency branch (including document inventory and review of the branch QMP, policies, SOPs, and QAPPS, as well as interviews with staff) at least once during the five (5) year cycle of the IDEM QMP. Branch quality system audits will be conducted in a manner consistent with "Guidance on Assessing Quality Systems, USEPA QA/G-3" and concepts presented at the USEPA Region 5 sponsored training on quality system assessments presented in Chicago, in October 2006.

The goal of each audit will be to assess the content of "in place" quality documents (branch QMPs, policies, SOPs, and QAPPs) and the degree to which they are followed by staff. The assessment will include recommendations from the Agency QA Manager on how to improve documentation to facilitate even greater use of quality system standards and requirements in daily work practices. Audit planning, reporting, and resultant commitments to document revisions and new quality system goals will involve the participation of the appropriate levels of IDEM management (Assistant Commissioners, Branch Chiefs, and Section Chiefs). With respect to assessing the various branch level QMPs the quality managers will:

A. Assess each branch QMP at least once during each five (5) year USEPA -imposed QMP approval cycle
B. Review the branch QMP prior to any assessment to identify areas that may need improvement

C. Review all branch policy, SOP, and QAPP documents for consistency with Agency standards and quality document maintenance schedules
D. Identify those aspects of the quality system to present to the Branch Chief as areas that should be the focus of the branch assessment
E. Meet with the Branch Chief and designees to plan what aspects of the quality system need the most scrutiny during the assessment (including both the area(s) identified by the Agency QA Managers as needing improvement, and areas the Branch Chief has identified for evaluation)
F. Determine from the BC whether the branch has been assigned new areas of responsibility requiring quality documentation
G. Interview branch staff for their input on the quality, clarity, accuracy, and usefulness of branch policies, SOPs, and QAPPs; and their suggestions or comments regarding additional areas or activity that may need improvement
H. Evaluate and comment on branch training plans, requirements, and records
I. Determine the degree to which consistency with the branch quality system was incorporated into employee work performance evaluations
J. Develop an inventory of the successful and positive attributes of the branch quality system (QMP and supporting documents, and their quality)
K. Develop recommendations to the Branch Chief regarding areas of the quality system in need of improvement
L. Work with the Branch Chief and Agency executive staff to develop a consensus plan and schedule for implementing Agency QA Managers recommendations

Review of the IDEM Agency-wide QMP, that umbrella document that serves to address Agency-wide QA issues and to unify the various IDEM branch QMPs and their associated QA documents into a single, coherent quality system, also shall be done the by the Agency QA Managers. The IDEM QMP will be reviewed and revised as necessary at least once during the five year period during which it has USEPA Region 5 approval.

2.2.3. Training Plans include:

The Agency has several training initiatives in place that relate directly or tangentially to the Agency's quality system, including:

- Performance expectations tied to the "pay for performance" (discussed below in Part 3.2.) program: Employee work profile/performance plans require each employee and their supervisor to develop an annual "plan" as part of the annual performance evaluation. The plan identifies the quality objectives, assignments, and/or responsibilities to be met and establishes the desired task outcomes as well as the standards for how well, how much, and how quickly the set outcomes are to be completed.
- Ongoing SOP/Policy development training that has been completed by more than 42% of the Agency and will continue to be presented about bi-monthly to any additional staff designated to participate more actively in the development of the IDEM quality system at the Agency, branch, section, or environmental activity level.
- Pending USEPA Region 5 provided QAPP training for science support staff and grant project directors;
- Developmental training for employees on the Agency's management track.

2.2.4. QA Project Plan (project-specific quality documentation):

A Quality Assurance Project Plans (QAPP), required for all work involving verifiable environmental data or environmental technology used as part of a remediation activity.

2.2.5. Data Verification and Validation (data assessments):

Done by those staff involved in QAPP development and associated sampling or other data gathering; branches including:

- Office of Air Quality (OAQ) Ambient Monitoring Branch
- OAQ Programs Branch (Technical Support and Modeling Section)
- Office of Land Quality (OLQ) Science Services Branch
- OLQ Remediation Services Branch
- Office of Water Quality (OWQ) Assessment Branch
- OWQ Watershed Planning Branch

3. Personnel Qualification and Training

Purpose – To document the procedures for assuring that all Agency personnel have the necessary skills to effectively accomplish their work

3.1. Description of Training Policy

Agency-wide training and refresher training, required of all Agency staff, is addressed below. Any program area or environmental activity specific training needs are addressed in the branch-level QMPs.

3.1.1. IDEM Agency-wide trainings, required for all Agency staff include:

- Completion of the following training classes within the first six (6) months of employment at IDEM:
  - New Employee Orientation;
  - Work Place Harassment prevention for all staff;
  - State Ethics Training for all staff;
  - Information Users Resource Agreement (IURA)
- Annual completion of refresher training in Work Place Harassment Prevention;
- Bi-annual completion of refresher training in Ethics for Agency staff; and
- Completion of Pollution Prevention Training when it is presented, which is on an occasional basis. (Agency-wide pollution prevention was held in 1993, 1998, and in May and June of 2006.)

Employee participation records are maintained in IDEM's Office of Human Resources.

3.1.2. Trainings for specific employee groups

In addition, there are trainings that are coordinated at the Agency level, but are not intended for all Agency staff; only for specific groups of staff:

3.1.2.1. Trainings required for all managers:

- Americans with Disabilities Act
- Comprehensive Employee Relations Training (CERT)
- Conflict Management OR Preventing Violence in the Workplace
- Diversity in the Workplace
- Ethics for Supervisors and Managers
- Employee Discrimination
- Family Medical Leave
- Interpersonal Dynamics
- Payroll Systems Review
- Personnel Rules
- Performance Appraisal
- Selection, Interviewing, and Hiring
- Situational Leadership

- State and Agency Personnel Policies and Procedures

3.1.2.2. Training required for all Agency staff that do field work:

All Agency staff that do field work must be certified as capable and eligible to work in areas that may be contaminated with hazardous waste materials or constituents, or that may pose other health or safety threats or require the use of personal protective equipment (PPE). They shall comply with the Agency Health and Safety Training Policy, A-030-OEA-07-P-R1, August 13, 2001, and the Medical Surveillance Program Policy, A-032-OEA-06-P-R1, July 23, 2002.

- Agency staff that do field work must have HAZWOPER 40-hour or 24-hour training (as provided by the Agency through a contractor) as required under 29 CFR 1910.120, and must also have annual 8-hour HAZWOPER update training. HAZWOPER training (and retraining) topics are identified and developed by the Agency Health & Safety Office and the training contractor, in consultation with the respective program areas with Agency staff that do field work. Individual staff training records are maintained by the Agency Health & Safety Director.

In conjunction with this training requirement, the Agency Health & Safety Office must maintain a medical surveillance program (as required under 29 CFR 1910.120) that includes the following medical records on all Agency staff that do field work:

1) Medical surveillance report certifying the staff person is physically able to perform; and
2) Medical confirmation that the staff person is physically capable of working while wearing a respirator.

Medical records that contain social security numbers are confidential and are stored under lock until such time as they can be shredded.

- Knowledge of the Facility Specific Safety Orientation Policy, A-021-OEA-06-P-R0, July 1, 2006, and viewing of facility safety orientations prior to conducting routine inspection activities.

Any Agency staff that do field work that intend to make an unscheduled visit to a potentially hazardous source or facility must first check with the Agency safety officer to see if site specific safety training video associated with that source or facility is available.

3.1.2.3. Agency Staff Assigned to Develop Written SOPs and/or Policies:

Training also is available to staff that may be involved in developing and writing SOPs or policies. The training materials are referenced in the table in 2.1. and in section 2.1.4.

3.1.2.4. Agency Staff Designated for Public Records Training:

Public Records Training – The Central File Room and other Agency designated staff involved in records management attend training developed and conducted by the Indiana Commission on Public Records (ICPR). This training discusses records retention schedules, storage of and proper destruction of records. This training is vital to provide Agency staff with the resources needed to fulfill the requests for information we receive on a daily basis. The IDEM Public Records Requests Policy A-017-OEA-06-P-R0, April 1, 2006, establishes how all Agency staff responds and fulfills all information requests. If Agency staff should every have a question regarding public records they have two avenues to answer their questions. The IDEM Office of Legal Counsel provides guidance regarding information requests that involve subpoenas or other litigation proceedings. The Office of the Public Access Counselor is an Agency that was created in order to provide advice and assistance concerning Indiana's public

access laws to members of the public, government officials and their employees.

3.2. IDEM hiring practices and their impact on the expertise and training needs of Agency staff

A factor that has influenced the quality and institutional knowledge base of Agency staff in a very positive way is Agency's hiring practices. Listings in the Indiana Job Bank for open Agency technical positions require that successful candidates meet specific requirements for experience and/or education. Generally, the positions require five (5) to seven (7) years of related professional experience or a college degree or degrees with an equivalent number of years of study with a concentration in biology, biophysics, business administration, cartography, chemistry, engineering, environmental affairs, environmental science, geology, mathematics, microbiology, natural resources, physics, public administration, public affairs, public health, or a related area. These requirements ensure that new employees have enough technical and scientific background to be trainable for specific work they would do if selected to fill an open position. Agency staff/managers with the responsibility for interviewing and hiring new staff now use a PeopleSoft™ electronic system to more quickly and efficiently identify those applicants most eligible for consideration.

The policies and processes associated with conducting the primary activities undertaken by the Agency (permitting, inspecting, compliance assistance, remediation, and enforcement actions) during the course of carrying out the Agency's mission do not change much over time. While there are occasional program changes that require additional new training of existing staff, the greatest emphasis on job training is understandably focused on new and transferring employees.

Because Agency staff must re-apply for any new position assignment, hiring managers have an opportunity to reevaluate past employee job performance prior to moving interested/eligible staff into a new position level. This practice also ensures those staff with the most experience and institutional knowledge and memory are mostly likely to advance to more responsible positions and to populate many of the positions in the chain of management review discussed above.

In 2006, the Agency celebrated its 20th Anniversary as a state environmental agency, and many staff have been with the Agency throughout that time. The Agency is committed to capturing the work experience and institutional knowledge of these long-serving Agency staff in SOPs and written policy documents. In conjunction with the SOP/policy development initiative, Agency management also is evaluating how best to implement training plans at all levels to ensure even more efficient staff training in the future.

The Agency is further investing in the preservation of its institutional knowledge base through the implementation of the State's "pay for performance program". Under this program, staff that most strongly contributes to Agency performance, and likely have the most to contribute to the overall Agency institutional knowledge, reap the greatest benefit, and therefore are more likely to remain with the Agency to help to perpetuate the Agency's institutional knowledge.

3.3. Training QA Procedures

3.3.1. Ensuring appropriate training:

Except for the Agency-wide training requirements listed in 3.1., all other training requirements for Agency staff are addressed at the branch-level and in the branch-level QMPs associated with this Agency-wide QMP. These include:

- Training approval documentation;
- Training needed for each position type, as listed on Employee Work Profile/ Performance Plans; or
- Additional staff training needs based on program requirements.

3.3.2. Meeting requirements for formal training:

It is the role of the supervisor to ensure that employees maintain all appropriate credentials, accreditations and/or licenses. The Agency also has a commitment to employee development, supporting employee attendance and participation in conferences and training seminars on topics related to Agency business. These opportunities for training and professional interaction and development may be sponsored by USEPA, Environmental Council of the States (ECOS), universities, professional associations or other environmental-related organizations. Agency staff also may apply for tuition reimbursement.

3.3.3. Identifying need for retraining:

The work product review process provides managers with the opportunity to identify any training or retraining needs employees may have. Work that is less than adequate can be used as a strong indicator that additional employee training or retraining is necessary.

The Agency QA Managers provide or monitor and track all QA training provided to Agency staff. Therefore, Branch Chiefs, Sections Chiefs, or designees providing QA-related training to staff shall notify the Agency QA Managers of such training.

4. Procurement of items and services

Purpose – To document the Agency's purchasing procedures

4.1. Reviewing and approving procurement documents

Approximately 80% of all purchases are routine. IDEM has a strong interest in assuring that all goods and services meet the highest technical and scientific standards. The Agency has in place a very rigorous procurement review process to ensure that goods and services purchased by the Agency are necessary and meet all the technical specifications and requirements of the tasks for which they are being procured. Much of the scrutiny associated with purchase-related quality assurance is done at the program branch or section level, where environmental activities are conducted. It is at this level, that the procurement process begins with a request from program staff "requesters" who establish the desired characteristics of the goods or services to be purchased and determine the specifications that must be met to ensure the quality of the good or service. Each program area has designated requesters that have been formally trained (See http://www.in.gov/idoa/services/proctraining/) in the acquisition request process by the Indiana Department of Administration (IDOA). That process is detailed in the IDOA Procurement Manual. This quality assurance aspect of procurement is addressed in the branch level QMPs.

As depicted in the flowchart below, the Agency has an electronic (E-Procurement) purchase approval system. This system is built on a People-Soft™ platform that reflects and relies upon the same chain of managerial review and approval used by the Agency for other decision-making processes. Each program area has determined which managers need to be involved in the procurement approval process, and each such manager has been trained in the electronic approval process. Procurement requests originate at the program level and must undergo at least five and potentially as many as eight levels of managerial and business review prior to final approval.

Among the elements reviewers look for when evaluating procurement requests are:

- Confirmation that the program requesting the purchase has verified, to the extent possible, that the vendor(s) providing the good or service requested is properly certified or accredited to perform the tasks, or that the goods purchased carry some assurance of quality performance and adherence to required specifications;
- Confirmation by accounting staff that the purchase will be charged to the correct account, and that the account has adequate funds; and
- Confirmation by purchasing staff that the appropriate solicitation method has been used and that the requestor has provided adequate justification for the purchase.

If at any point in the review process it is determined that the requestor has not provided adequate information or justification regarding matters of quality assurance or any other issue, the requisition is returned to the requestor for correction or additional information.

Requests are also reviewed for compliance with numerous state purchasing requirements or approvals. Agency procurement is audited biannually by the Indiana State Board of Accounts, and is sometimes reviewed by USEPA Region 5.

Agency purchases of greater than $2,500 also must go through a formal contract process as established by the IDEM Contract: Professional Service Contract Policy A-013-OEA-07-P-R1, May 1, 2007 (See Appendix D). Contracts for less than $75,000 must go through the Request for Quotes (RFQ) process to solicit competitive quotations from potential contractors. A minimum of three potential sources, at least one of which is either a Minority Business Enterprise (MBE) or a Women's Business Enterprise (WBE), must be solicited for quotes.

Contracts for more than $75,000 must go through the Request for Proposal (RFP) process, as authorized under Indiana law IC 5-22-9. RFP is a formal process to procure goods or services for which price is not the sole factor in the selection of a respondent or respondents. The RFP process requires each state agency to provide documentation that outlines available funds. It must also specify the requested goods and/or services sought. Work proposals are then evaluated by the Indiana Department of Administration (IDOA) for optimal value to the Agency before the Agency selects the contractor.

The extent of the approval required is dependent on the scope of the purchase involved. The Assistant Commissioners of the various Agency programs, or their designees, review all requisition requests that require a contract. IDEM's Office of Legal Counsel advises Agency staff concerning federal and state legal requirements; reviews draft contracts and Requests for Quotes, assists with the development of contract language, and approves contracts for form and legality. Contracts of up to $100,000 are reviewed by the IDEM Assistant Commissioner of External Affairs. Contracts of greater than $100,000 are reviewed by the IDEM Commissioner.

In addition, the Contract: Professional Service Contract Policy, A-013-OEA-07-P-R1, January 1, 2007, requires any contractors hired to abide by all Agency policies and Standard Operating Procedures. Any contractor that lobbies the Indiana executive branch (including IDEM) to delay, oppose, promote or otherwise influence the outcome of an executive branch (IDEM) action must register with the Indiana Department of Administration, as required under the Indiana Administrative Code, 25 IAC 6.

Regarding Agency purchases of services using federal funds are passed by IDEM to third party applicants in the form of grants are treated as contracts. The Agency shall review the quality management plan (QMP) of any prospective contractor being considered for a contract of $100,000 or more. The review of prospective contractors' QMPs will be done by the Agency QA Manager, the Branch Chief or a designee of the contracting program, and the Assistant Commissioner of External Affairs or a designee.

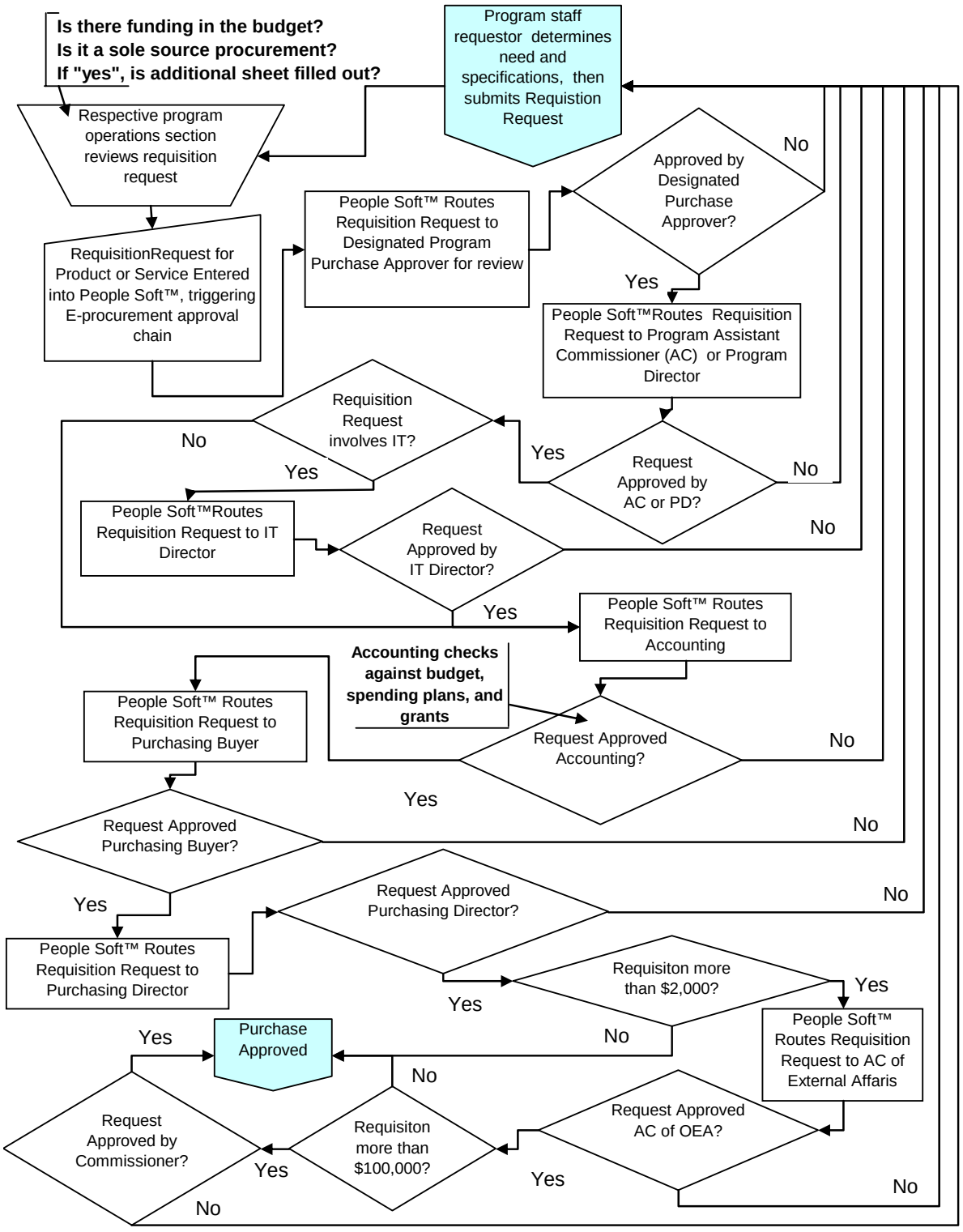
When IDEM uses federal funds for work to be performed by Agency staff, the IDEM Grants Management Policy, A-018-OEA-06-P-R1, March 1, 2007, (See Appendix D) requires (see Part 6.2.) that QAPPs be developed and implemented for each grant that "involves the acquisition of environment data generated from direct measurement activities, collected from other sources, or complied from computerized databases and information systems. The Agency has a PeopleSoft™ Grants Module that tracks all grant spending, and related compliance with grant requirements such as QAPP development, implementation, and reporting.

As stated in the Agency's Policy, SOP, and QAPP Documentation Policy, A-050-OEA-07-P-R0, February 15, 2007 (See Appendix A) the content of all Agency QAPPs should follow the Agency template, which is consistent with the content requirements of USEPA QA/G-5, except if other USEPA or USEPA Region 5 personnel provide an alternate QAPP format, or

data gathering requirements established by statute or rule are required instead.

To summarize, the focus of this IDEM 2007 QMP is on Agency-wide procurement processes and quality assurance measures. The principle quality assurance and quality control steps taken by the Agency occur at the branch, or environmental activity level, and so are addressed in the respective branch-level QMPs. The branch-level QMPs identify any program specific processes used to establish what is needed, what specifications the needed good or service should meet, and what post-procurement process is used to confirm that the goods and services obtained meet the required standards.

IDEM Procurement Review Process



4.2. Post-procurement product/service QA procedures

For routine, off-the-shelf products like paper, supplies, equipment, or software, the quality control process is very straightforward: was the number ordered the number delivered, and once it comes out of the box, does it work as anticipated? Products that fail to perform may be returned by notifying Agency purchasing, which handles all returns.

Quality or performance problems with more sophisticated pieces of equipment generally are addressed by the vendor through the service contracts or warranties included as part of the contract (all purchases over $2,500 require contracts). If a vendor cannot adequately address program area dissatisfaction with equipment or service performance, purchasing may be notified to pursue return of the product. In addition, purchasing may downgrade or remove a vendor from the list of eligible vendors for consideration in future purchases and may refer the matter to the Indiana Department of Administration Contract Resolution Team.

5. Documents and records

Purpose - To document appropriate controls for quality-related documents and records

5.1. Introduction

5.1.1. Records retention:

According to IC 5-14-3-3, any person may inspect and copy the public records of any public agency during the regular business hours of the agency, except as provided in IC 5-14-3-4. A request for inspection or copying must identify with reasonable particularity the record being requested and be, at the discretion of the agency, in writing on or in a form provided by the agency.

Agency program areas and the IDEM Planning and Assessment Office (PA) and the Office of Legal Counsel (OLC) work with the records management division of the ICPR to develop retention schedules for the handling, maintenance and disposal requirements of Agency records. Record retention schedules are based on the content of the record and not on the media type (paper, digital, etc.). ICPR-approved Agency record retention schedules can be viewed on the Internet at: http://www.state.in.us/serv/icpr_retention.

Agency documents still being processed or under development are deliberative, and are managed and stored by the individuals involved in the process. Once the work process is complete and the documents become public records. One of the several record storage mechanisms for work products such as Permits, Inspection Reports, Orders, etc. are selected. These include:

- Record storage within the program area;
  The records stored in programs areas are deliberative and are being used by program area staff in the normal course of business.
- Record storage in the Central File Room;
  Source and/or facility-specific public records are located here. These include, but are not limited to, permits (or permit modifications, variances, or, renewals), inspection reports, remediation actions, administrative orders, notices, and any other public records. The Central File Room is in the Indiana Government Center North Building, 100 N. Senate Avenue, Indianapolis, Indiana, 46204, east-end of the 12th floor. It is open to the public from 8:30 am to 4:30 pm Monday through Friday, excluding Indiana State Holidays.
- Record storage at the State Records Center;
  Based on ICPR-approved retention schedules, records stored in the Central File Foom are properly boxed and transferred to the Indiana State Records Center, 6400 East 30th Street, Indianapolis, IN 46219. There, Agency records are stored by record type in ICPR approved boxes on shelves.
- Record storage at the Indiana State Archives;

The Indiana State Archives is the final repository for all Agency records of permanent legal or historical significance. When the Agency transfers its records to the state archives, the title to the records also is transferred. Records held by the archives are open to review and are available for examination. Compliance with proper boxing and labeling procedures at the time records are transferred ensures prompt retrieval. The Indiana State Archives is located at 6440 East 30th Street Indianapolis, Indiana 46219.

Record storage within the program areas is through the use of file cabinets (which are to be locked if security requires). Programs that store records within their own program area address storage in the branch-level QMPs. Additionally, branch-level QMPs address records preparation and maintenance activities required prior to records being placed in the Central File Room.

5.1.2. Central File Room:

In 2000, IDEM established the Central File Room to reduce duplication of staff maintaining files and to facilitate access to public records. The Central File Room staff have a primary focus to provide assistance to the public or Agency staff to find the requested public records. The secondary focus is to file the records that come into the Central File Room into the appropriate public file for viewing. The filing system used in the File Room is program specific and new storage files are created by Central File Room staff members. Files in the Central File Room are stored on shelves or in labeled boxes.

Records retention and archiving requirements are the responsibility of program level staff and are described in branch-level QMPs and in record retention schedules. Records stored by the program areas and by the Central File Room are sent to the State Records Center for longer term storage, based on their associated ICPR-approved retention schedules. Records are sent to the State Records Center in approved ICPR labeled boxes for this longer-term storage.

"Records" can include information captured or stored in a variety of media, including electronic records. The Central File Room is moving toward electronic data storage. This will ultimately allow the public to view and print public documents from remote computers.

5.2. Identification of QA-related records

As stated in Part 5.1.1., branches that administer Agency environmental activities/programs are responsible for working with IDEM's Office of Legal Counsel to identify records subject to control (management, storage, and disposal), using the Indiana Commission on Public Records (ICPR) approved records retention schedules.

The Agency retains all records that are subject to Indiana Code (IC) 5-15-5.1 and thus qualify as "retainable records." This statute defines "Record" as "…all documentation of the informational, communicative or decision-making processes of state government, its agencies and subdivisions made or received by any agency of state government or its employees in connection with the transaction of public business or government functions, which documentation is created, received, retained, maintained, or filed by that agency or its successors as evidence of its activities or because of the informational value of the data in the documentation, and which is generated on:

(1) Paper or paper substitutes;

(2) Photographic or chemically based media;

(3) Magnetic or machine readable media; or

(4) Any other materials, regardless of form or characteristics.

Record preparation and maintenance procedures for file storage, either within the program area or in the Central File Room, is discussed more specifically in the Branch-level QMPs All branch retention schedules must be prepared in accordance with Indiana Commission on

Public Records (ICPR) requirements and all record retention schedules are reviewed and approved by the ICPR.

5.3. Record handling processes

Topics in this section, listed below in 5.3.1 through 5.3.7 are derived from "USEPA Requirements for Quality Management Plans, USEPA QA/R-2," Part 3.6. Some of these topics are more applicable at the branch level and are discussed in the respective branch-level QMPs. Only those topics that are applicable to the Central File Room and address Agency-wide document handling activities are discussed below.

5.3.1. Record preparation:

The contents of Agency files are prepared by Agency program (air, land, and water) staff. Central File Room staff maintain records sent to the file room for access by Agency staff and the public. Central File Room staff file, retrieve, and copy records upon request and also track records on loan to Agency staff. Agency staff adheres to the Indiana Public Records Act (IC 5-14) and the IDEM Public Records Request Policy, A-017-OEA-06-P-RO, April 1, 2006, with respect to providing records access.

Agency staff must follow the procedures in the Public Records Request policy, including:

- Producing State of Indiana identification badge when requesting records from the Central File Room or working in the Central File Room.
- Completing the Agency public information request form for each record requested.
- Maintaining records received in the condition they are received from the Central File Room. Records checked out from the Central File Room are not transferable to other Agency staff. Indiana Code 5-14-3-7 states that a public agency shall protect public records from loss, alteration, mutilation, or destruction, and regulate any material interference with the regular discharge of the functions or duties of the public agency or public employees.
- Agency staff can check out records for a thirty (30) day period. When files are returned back to the Central File Room they are required to be signed back in to verify their return.

Citizens making public records requests also are subject to the requirements of the IDEM Public Records Request Policy, and must:

- Provide enough description and detail about the information requested to enable the Agency to accurately identify and locate the records requested;
- Cooperate with the Agency's reasonable efforts to clarify the type or amount of information requested;
- Not to alter original records according to IC 5-14-3-7; and
- Keep all records in the Central File Room public review area.

Members of the public may request copies of public records. The first 100 pages are considered gratis, after which the Agency assesses a $0.10 per page fee. Record larger than 11 ½ x17 inches are $0.70 per page.

5.3.2. Record review:

The content of all record containing files is the responsibility of the individual program areas, and the review of file content is addressed in the respective branch-level QMPs.

5.3.3. Record approval:

Records stored in the Central File Room are developed and approved at the branch level. They are stored in the file room according to Branch -specific retention schedules developed in conjunction with the IDEM Office of Legal Counsel. The public may use equipment and

materials to scan or copy public records provided they bring it to the public file room to use in the public viewing area.

5.3.4. Record issuance:
Agency Decision announcing records are issued at the program level. Therefore, record issuance is addressed in the branch-level QMPs.

5.3.5. Record use:
Central File Room staff responds to record requests according to the Access to Public Records Act. A $0.10 per page copy fee is charged for each page copied after the first 100 pages. File room staff prohibit public access and use of confidential records except as allowed under the Indiana Public Records Act IC 5-14-3. Only authorized Agency staff may view confidential records.

5.3.6. Record authentication:
All measures to authenticate records stored in the Central File Room are taken at the program branch or section level. However, the Central File Room provides letters of certification to verify that copies of records are accurate reproductions.

5.3.7. Record revision:
According to IC 5-14-3-7 a public agency shall protect public records from loss, alteration, mutilation, or destruction, and regulate any material interference with the regular discharge of the functions or duties of the public agency or public employees. Therefore, Central File Room staff helps ensure that public records are not altered.

5.4. Ensuring that records accurately reflect completed work

Records produced by the Agency accurately reflect completed work. This is particularly true with permits, licenses, inspection reports, and documents issued by the IDEM Office of Compliance & Enforcement (Notices of Violation, Orders, etc.)

For other Agency work products, the work completed is separate from the records reporting on the completed work. Examples are outreach, the implementation of grants, sampling activities, or site specific cleanup actions. The method for ensuring that records accurately reflects work completed is addressed in a case-by-case manner in the branch-level QMPs.

5.5. Record maintenance

Topics 5.5.1 through 5.5.9 are derived from “USEPA Requirements for Quality Management Plans, USEPA QA/R-2,” Part 3.6. Some of these topics are more applicable at the branch level and as such, are discussed in the respective branch-level QMPs. Only those topics that are applicable to the Central File Room, and address Agency-wide record maintenance activities are discussed below.

5.5.1. Transmittal:
Central File Room staff transmit records when copies are requested by record requestors, and when records are prepared for transfer from the file room to the State Records Center or to the State Archives. The Agency Records Retention Policy lists specific requirements for the preparation of records to be sent to the State Records Center or State Archives, including:

- The type of storage boxes to be used;
- The limits on types of records that can be stored in the same box;
- Use of a standardize filing system;
- Storage box labeling requirements;
- The inclusion of retention schedule dates on box labels;

- Requirements on the order in which boxes should be arranged;
- The use of records transmittal receipt forms; and
- The provision by the State Records Center of a receipt with shelf location information.

5.5.2. Distribution:
The Central File Room staff distributes copies of public records to the requestor.

5.5.3. Retention:
Branch Level retention schedules address the proper removal and destruction of public records.

5.5.4. Access:
File room staff is required by law to provide access to all public records, or to cite a reason why such access cannot be provided.

5.5.5. Preservation:
All records are retained in accordance with Branch level record retention schedules.

5.5.6. Traceability:
All records stored in the Central File Room are developed by Agency staff or by persons completing IDEM state-approved forms.

The tracking of records done by file room staff is related to records removed and returned from the Central File Room by Agency staff. Staff that check records out from the Central File Room are required to maintain the records they receive, to return the records in the condition in which they were received, to not alter borrowed records, and to not transfer records from the file room to other Agency staff. Agency staff also must return records after thirty (30) days. Agency staff may copy or scan records checked out from the Central File Room.

5.5.7. Retrieval:
Agency staff requesting to remove records from the Central File Room must first complete an "out slip" request. File room staff use the form to retrieve the desired records.

5.5.8. Removal of obsolete documentation:
The removal of obsolete records and files from the Central File Room is the responsibility of program staff. Removal of obsolete records by program area staff, consistent with appropriate retention schedules, is discussed in Branch level QMPs.

5.5.9. Archiving and/or disposal:
The archiving or disposal of records and files from the file room is the responsibility of program staff, and is addressed in Branch level QMPs.

5.6. Document Maintenance

The control of Agency quality assurance related documents; the QMP, branch QMPs, and policies, SOPs, and QAPPs is the responsibility of the Agency QA Managers. Requirements for the applicability, development, content, use, maintenance, storage, archival and approval of policies, SOPs, and QAPPs as well as storage of the IDEM Agency-wide QMP and branch QMPs is addressed in Part 6 of the Agency Policy, SOP, and QAPP Documentation Policy (Appendix of the QMP).

5.7. Compliance with statutory/ USEPA recordkeeping requirements

As described in Part 5.1, the Indiana Commission on Public Records (ICPR) requires State agencies to develop records retention schedules for records that are subject to Indiana Code

(IC) 5-15-5.1 and thus qualify as "retainable records." The Agency also takes all other applicable state and federal legislation when developing record retention schedules. The IDEM Office of Legal Counsel verifies that Agency records retention schedules meet applicable state and federal record keeping requirements before draft records retention schedules are sent to ICPR for review. As a result, the Agency and Agency environmental activity areas, in conjunction with the ICPR, use a process that always ensures compliance with all applicable statutory and USEPA record keeping requirements.

5.8. Procedures for implementing chain of custody for evidentiary records

Chain-of-custody is not a widely used process throughout the Agency. It is primarily used at the Branch levels when samples are taken and it is necessary to preserve the integrity of the samples. At all Branch levels, when public documents are created they are sent to the Central File Room for filing into the appropriate public file. Some Branches choose to use an internal chain-of-custody document attached to the public record to ensure that Branch level procedures and policies are followed. Those chain-of-custody procedures will be addressed in Branch level QMPs.

Records, including electronic records and e-mail, that relate to a matter on the litigation hold list must be preserved as evidence even if the Agency has a record retention schedule that allows the record to be destroyed.

6. Computer Hardware and Software

Purpose – To document how IDEM addresses all computer-use related issues common to the entire Agency and ensures that computer hardware and software satisfies the Agency's requirements.

Shared Service Roles – Planning, development, deployment, control, use, and maintenance of the computer infrastructure (i.e. servers, network, desktops) at the Agency is shared between IDEM's Information Technology Office (IT) and the State's Indiana Office of Technology (IOT). The topic in Part 6.1. describes the Agency's guidance documents for Agency-wide technologies and identifies which of the respective offices (IT or OIT) is responsible for each of the various hardware or software issues.

Shared Service Background - The Indiana Office of Technology has consolidated the infrastructure hardware and services of all Executive Branch offices under their control. The consolidation extends across the nearly ninety (90) state and quasi-state agencies. IOT has established a set of Service Level Objectives that describe the nature of those services and the level of service to be provided.

Business Systems Consultants' (BSC) Roles and Responsibilities
Each BSC is assigned to one or more Program Areas or Offices. In that capacity they:

- serve as the initial and primary point of contact with the Program Areas,
- assemble basic needs and problem definitions prior to application development consideration,
- develop application requirements for all application development projects
- develop user documentation for all Agency developed applications and provide training to users,
- perform appropriate duties as part of a Project Team.

Project Managers' (PM) Roles and Responsibilities
The PMs play a central role in developing medium to large, complex, multi-program area enterprise application projects. In that capacity they:

- work with the appropriate BSC throughout the process,
- assure that all resources are managed

- serve on the Application Development Team with the BSC and Application Developers,
- provide background on the software application to the Application Developers.

Application Development (AD) Team's Roles and Responsibilities
The members of the AD Team create and manage IDEM-specific application software. In that capacity they:

- serve as part of the Application Development Team with the BSC and PM,
- manage and interact with any contracted third party software application developer,
- create/develop, test, and manage IDEM-specific application software
- perform database administration, security, installation/configuration, back-up and recovery.

Information Technology Office Administration Assistant's Roles and Responsibilities
The Administrative Assistant plays the pivotal role in meeting Agency hardware and software needs by:

- preparing and expediting requisitions for hardware and third party application developers, and
- Interacting with Agency and state procurement staff and policies.

6.1. Interacting with Agency and state procurement staff and policies

Topics in this section, listed below in 6.1.1 through 6.1.5 are derived from "USEPA Requirements for Quality for Quality Management Plans, USEPA QA/R-2," and through an Information Resources Use Agreement (IRUA) between IDEM and The Indiana State Indiana Office of Technology (IOT). The term "Information Resources" includes all state hardware, software, data, information, network, personal computing devices, phones, and other information technology. To use Information Resources IDEM has agreed to adhere to the provisions of this agreement, which are established to ensure security and inform users of the conditions of use.

6.1.1. Processes associated with software/hardware testing:

Commercial Off the Shelf software (COTS) (i.e. ESRI-ArcGIS) testing process is done through the Indiana Department of Administration (DOA) contracting/procurement policies. Procedures and enterprise software such as Microsoft Office or McAfee Virus procurements fall under IOT control.

In-house software Development (I.e. Communications Tracking Database) testing process is done through the following processes:

- Software Development Document (SDD); Data Management Guide (DMG) at S:\Agency/Enterprise Data Initiative\Data Management Guide2005_rev10262005.doc
- Data Standards (DS) (EDSC/Security, etc.)
- IDEM Testing Procedures (ITS) -1st unit testing by developers to make sure requirements or scope or deliverables are met and then a 2nd unit User Acceptance Testing via plan by Project Managers.

Third -party Created software (i.e. ACES (Air Compliance and Enforcement)) testing process is done through DOA contracting/procurement polices and procedures; SDD; DMG; DS and ITS.

Desktop Hardware testing process is done through the DOA and adheres to State Quantity Purchase Agreements, and Exception Process.

Server Hardware and Network Environment Hardware testing process and related activities are controlled by the IOT (see IOT Service descriptions at http://www.in.gov/iot/directors/services-slo.html).

6.1.2. Processes associated with software/hardware use:

Commercial Off the Shelf software (COTS) (i.e. ESRI-ArcGIS); In-house software Development (I.e. Communications Tracking Database) and third -party Created software (i.e. ACES (Air Compliance and Enforcement)) software use is controlled through User manuals and the State Information Resource Use Agreement (IRUA) at: http://www.in.gov/iot/pdfs/ security/information resources_use_agreement.pdf and Desktop Hardware; Server Hardware and Network Environment Hardware use is controlled through the IRUA.

6.1.3. Processes associated with software/hardware maintenance. Any relevant maintenance, upgrade, backup processes:

Commercial Off the Shelf software (COTS) (i.e. ESRI-ArcGIS); In-house software Development (I.e. Communications Tracking Database) and third -party Created software (i.e. ACES (Air Compliance and Enforcement)) maintenance process is through the DMG. Desktop Hardware; Server Hardware and Network Environment Hardware maintenance process activities are controlled by the IOT.

6.1.4. Processes associated with software/hardware control (i.e. access control; security).Relevant to software, programs, or drives with limited access:

Commercial Off the Shelf software (COTS) (i.e. ESRI-ArcGIS) control process is through the following:

- Agency IT Director or the Agency Security Coordinator who submit access requests to IOT
- The IT Director who controls the licenses and media
- Information Resources Use Agreement (IRUA)
- The Information Security Framework (ISF) at: http://www.in.gov/iot/pdfs/security/information_security_framework.pdf

In-house software Development (I.e. Communications Tracking Database) and third-party created software (i.e. ACES (Air Compliance and Enforcement System)) control process is through the following:

- IT Director or the Agency Security Coordinator who submit access requests to IOT
- Information Resources Use Agreement (IRUA)
- Security and/or administration manuals
- Information Security Framework

Desktop Hardware control is through IRAU and activities controlled by IOT.
Server Hardware and Network Environment Hardware control is through ISF and activities controlled by IOT.

6.1.5. List documentation associated with hardware/software:

Commercial Off the Shelf software (COTS) (i.e. ESRI-ArcGIS) documentation is provided to requestor of software through ISF and IRUA

In-house software Development (I.e. Communications Tracking Database) documentation is maintained in document systems; complied in Software Developer Document and User manuals

Third -party Created software (i.e. ACES (Air Compliance and Enforcement System)) documentation provided by contractor as a deliverable

Desktop Hardware Manuals are left with the desktop

Server Hardware and Network Environment Hardware documentation are activities controlled by IOT

6.2. Hardware/software usage assessment and documentation

Agency hardware and software is selected specific to user requirements. If there is a change in user requirements, there is a change in hardware or software. With IT Director approval, the various Agency program staff work with IT Business Systems Consultants' (BSC), IT Project Managers, and the Application Development (AD) Team to institute these changes.

6.3. Hardware/software evaluation

Evaluating hardware and software to ensure it meets program needs, is done by program managers and staff working in conjunction with IDEM IT. For example, the Office of Land Quality (OLQ) inspection program worked with IT project managers to purchase Tablet PC's with Microsoft® Windows® XP Tablet PC functionality and wireless network connectivity. Together, OLQ and IT evaluated the purchased hardware and software to ensure it met user requirements and complied with applicable contractual requirements and standards. Branches may further discuss how they evaluate hardware and software and determine appropriate purchases in their branch-level QMPs.

6.4. Data QA/QC

Data Standards

IDEM's Data Management Guide (DMG) lists the Agency's enterprise data standards. The DMG was developed with input from all parts of the Agency. State, national, and international standards were reviewed and incorporated as appropriate. The DMG lists all aspects of database administration, security and data object naming conventions. All Agency staff are required to follow the DMG which is located at S:\AGENCY\Enterprise Data Initiative (EDI)\Data Management Guide2005_rev10262005.doc. The members of the Application Development Team, IT Project Managers as well as the Business System Consultants, ensure that applications and data produced internally, by contractors or collected by computers adhere to the standards contained in the DMG.

Compliance with data standards is ensured by reference to the DMG by all members of the Data Management Team before and during the development process. Compliance is further assured since all development requests must be reviewed and approved by the IT Director prior to the start of any development work.

7. Planning

Purpose – To document the Agency's planning process to ensure data or information collected is of the needed and expected quality for their desired use.

Planning: The EnPPA and the QMP
The Environmental Performance Partnership Agreement that IDEM has reached with the USEPA is the Agency's key work planning document. It establishes the primary work goals of each of the areas of environmental activity within the various Agency offices. Other Agency strategic planning efforts, state initiatives that are not established by the Agency, but that set goals the Agency must achieve or help to achieve, or deliverables associated with grants the Agency receives, also are factors that can drive the establishment of additional work goals. Each work goal that must be met by the Agency likely will require thorough planning to ensure quality results.

Having a good quality system in place provides an additional tool for developing new work goals. When there is a high degree of confidence in the data gathered to support existing work goals, that data sometimes can reveal new issues of concern that in turn prompt further planning and the development of future goals and priorities.

Generally, there are two types of quality assurance-related planning tools used by the Agency to satisfy the quality assurance component of Agency initiatives and work goals. The most appropriate tool for a given task is dependent on the type of task to be completed. To enable the various Agency programs' environmental activity working groups to consistently accomplish work

goals in a manner that also is consistent with USEPA and Agency quality system requirements, the Agency has a two quality assurance-related goals associated with its two planning tools

The first goal is for the various environmental activity areas within the Agency to plan and refine the work processes (SOPs) associated with producing the Agency's primary work product: decision announcing-records (such as permits, inspection reports, enforcement referrals, orders, cleanup plans, etc). Having good work processes in place will ensure that Agency decisions are quick, transparent, predictable, and fair.

The second goal is for the various Agency programs (the science support programs) that gather and analyze data used to support Agency decisions to have a project planning process in place ensures the data they provide is the correct data for the decision involved, and that the data produced is scientifically and statistically sound, having been subjected to a data verification and validation process. The more effective the planning done under the Agency quality system, the more likely the Agency's EnPPA goals will be effectively met.

7.1. Systematic planning process description

Agency work products are decision-announcing records, where the records, and their accompanying support documents, are finalized using a planned work strategy or process. The Agency's approved planning processes include:

7.1.1. Quality Assurance Project Plans (QAPPs):

QAPPs focus on the collection or generation of data and on the means by which the data are be verified and validated. This ensures that the data collected is scientifically defensible and adequately meets the needs and goals of the user and the project. QAPPs work for projects with a beginning and end point projects, and are referred to as "project QAPPs".

QAPPs are used by programs charged with gathering data on an ongoing basis (program QAPPS). In such cases, the planned ongoing gathering and verification of the desired data may done under a "program QAPP". The use of QAPPs ensures quality data that could in turn, be used to plan additional work that would also need additional QAPPs and could also require the planning of additional processes (SOPs).

7.1.2. Policies:

Written policies represent the plan for making a determination and reaching a decision in interpreting environmental statutes and rules. The Agency considers written policies tools that must be used in conjunction with QAPPs and SOPs.

Written policies also serve as a powerful planning tool for the regulated community. The more precisely they can understand Agency decision-making criteria, the more successfully they can meet required environmental standards. A well-informed regulated community is better able to maintain compliance, a primary Agency goal.

7.1.3. Standard Operating Procedures (SOPs):

SOPs are a planned methodology for the completion of a process or processes essentially repetitive in nature. SOPs are developed through the consensus of those that do the repetitive tasks and the managers responsible for the completion of those tasks. While QAPPs focus on data, SOPs focus on processes and upon the steps within the processes where decisions must be made. SOPs should be accompanied by policies that establish the criteria upon which the decisions are based. SOPs often are necessary to the implementation of QAPPs.

Staff developing site or time specific projects develop and use "project QAPPs." Meanwhile, the planning of ongoing data gathering and validation operations at the program level; which generally provides some form of scientific support for the air, land, or water programs, may result in the development of a "program QAPP," or some USEPA approved equivalent, such as lab manuals or operations manuals. These program QAPPs (or equivalents) often are

developed by Agency program staff in conjunction with, and under the scrutiny and review of their U.S.EPA counterparts.

Branches that use the Data Quality Objective process or some other systematic planning process in the development of project or program QAPPs (or other USEPA approved equivalents) discuss those processes in greater detail in their respective QMPs.

7.2. QAPP development process

7.2.1. IDEM branches that use QAPPs:

Some of the work done by the Agency involves the generation and/or use of data that can be verified or validated. The following Agency program areas perform scientific evaluations and use QAPPs, or equivalent documents, such as work plans or laboratory manuals:

- Office of Air Quality (OAQ) Ambient Monitoring Branch
- OAQ Programs Branch (Technical Support and Modeling Section)
- Office of Land Quality (OLQ) Science Services Branch
- OLQ Remediation Services Branch
- Office of Water Quality (OWQ) Assessment Branch
- OWQ Watershed Planning Branch

7.2.2. IDEM branches that generally do not use QAPPs:

The IDEM branches not listed above do not use QAPPs. As noted in the Introduction and part 1.4.1., a substantial part of all work done by the Agency involves the review of ongoing or proposed activities to determine whether the interpretation by multiple layers of reviewers are consistent with available data and with existing statute and rule. The Introduction states that the interpretive aspects of the review can mean that the quality control activities of this type of work cannot usually rely on data validation or verification because either there is no numerical data, or the data in use is not readily verifiable.

It is the establishment of standardized operating procedures (or SOPs) that are followed during the process of confirming consistency with data, rule, and law that provides the planning, or quality assurance component of this type of activity. Subsequently, it is the chain of hierarchical review and approval by several layers of increasingly experienced reviewers (most of whom are managers) that provides the quality control component of the SOP planning process.

Since the activities associated with evaluating proposed or existing actions for consistency with the rule of law generally do not generate, and may not use data that can be verified or validated, there is little opportunity to use the DQO (Data Quality Objective) process, or to develop and use QAPPs. On the contrary, those branches that do use QAPPs must still use the SOP. Technical SOPs are used to establish set procedures for their data gathering or data use activities. Administrative SOPs are used to document other, necessary step-by-step processes.

7.3. Processes associated with secondary uses of data

Any secondary use of data is identified in the respective branch-level QMPs.

8. Implementation of Work Processes

Purpose – To document how work processes will be implemented within the Agency to ensure that data or information collected is of the needed and expected quality for their desired use.

8.1. Processes for Ensuring Work Follows Planning and Technical Documents

Just as the Agency has processes in place for planning work (see Part 7.1.), it also has a

process in place for ensuring that planned work is performed according to the approved Quality Assurance Project Plan (QAPP) or Standard Operating Procedure (SOP). As stated above (see Part 7.1.), work planned by the Agency must follow either: 1) a QAPP, which is developed using the DQO (Data Quality Objective) process and which requires subsequent data verification and validation or 2) a SOP, which is developed using the collective knowledge and experience of the work group and its managers and used in conjunction with written policies to complete a work product that is reviewed by the Agency managerial, hierarchical chain-of-review.

At IDEM, QAPPs are "data-focused" plans that ensure that data gathered or generated to support Agency decisions are scientifically and statistically sound. SOPs are "process-focused" plans that help ensure that Agency decisions based on staff's best professional judgment are made as quickly as possible, and are consistent with available data, existing law, and applicable precedent. SOPs document processes. Processes generally include one or more steps that require some type of decision to be made. Because many Agency decisions must rely on best professional judgment and may be appealed, the best way to improve the decision-making process is to standardize the processes and criteria used to make decisions.

As part its quality system, the Agency established the Policy, SOP, and QAPP Documentation Policy, also referenced in the table in Part 2.1. It requires that decision-making criteria be documented separately from step-by-step procedure (SOPs) and from project plans (QAPPs).

Written policies are the third key building block of the Agency quality system. QAPPs are systematically planned by a working group to ensure the data gathered is the data needed and SOPs represent the consensus of best known method for doing a task as determined by those who do the work. Written policies are develop by managers and document, in their best professional judgment, the manner in which data and law may be interpreted to yield a decision that will withstand the scrutiny of appeal. Managers bring to the task of writing policies, the same experience and best professional judgment as is central to the Agency's hierarchical chain of review and approval, the central Agency Quality Control component of any Agency action for which the data verification and validation process is not applicable.

Work done using Quality Assurance Project Plans (QAPPs):
Data collected or generated as a result of planning done as part of a QAPP or other project planned using the DQO process, requires verification and validation. Verification ensures that the data was collected following the plan established in the QAPP and validation ensures the data gathered is appropriate for the intended use. IDEM branches that use QAPPs and the DQO process discuss their processes for data validation and verification in their individual branch-level QMPs.

Results produced using a QAPP generally are used to support permit, compliance, enforcement, or remediation-related decisions.

To further the Agency's commitment to the use of the DQO process and to use QAPPs in all appropriate circumstances, it has developed several documents (listed in table under 2.1.1.) to be used by Agency staff involved with the planning projects with individual data operations:

- The Policy, SOP, and QAPP Documentation Policy establishes content requirements for QAPPs based upon the requirements of "USEPA Requirements for Quality Assurance Project Plans, USEPA QA/R-5." It also identifies the roles of project managers, program managers (branch and Section Chiefs), and Agency (QA) Managers in QAPP development, review, approval, and use;
- The "QAPP Development and Approval SOP," which details QAPP development and review procedures;
- The QAPP Template, which includes the 24 USEPA -required QAPP elements;
- The QAPP Review Checklist based on USEPA's checklist; and,

- The IDEM Grants Management Policy, A-018-OEA-07-P-R1, March 1, 2007, which requires the grant coordinator to develop a QAPP for any grant that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or complied from computerized databases and information systems.

For sub-contracted services that involve the collection, or analysis of verifiable environmental data, the Agency requires that the program overseeing the contract either develop a QAPP for the contractor, or require the contractor to develop a QAPP as part of the contract. This requirement also was established by the IDEM Grants Management Policy, A-018-OEA-07-P-R1, March 1, 2007. It requires that the DQO process be used to develop the grant proposal, the contract solicitation, and the associated QAPP.

Work done using SOPs:
Many of Agency's work products are "decision-announcing-records," (i.e. the application was determined to be complete, or it was determined to be incomplete; the permit was issued, or denied; the source or facility was in compliance, or it was out of compliance; the plan was approved, or not approved).

To ensure that each "decision-announcing-record" the Agency produces is completed quickly, consistently, predictably, and as fairly as is possible, requires that it standardize its decision-making process. SOPs always include certain steps at which some decision-based on decision-making criteria established by management and documented in policy, must be made. SOPs also ensure that the decision-making itself is standardized to the extent possible.

When staff is developing SOPs, they also will be identifying the parameters of a decision that must be made based on decision-making criteria established by management. The Agency uses written SOPs and written policies (including State Environmental Board reviewed Non-rule Policy Documents, and managerial decision-making guidances and directives) to standardize its work processes.

Using SOPs, in conjunction with associated documents, ensures that the same steps are taken each time decisions of a similar type are made. The repeated production of "decision-announcing-records," all of which are similar in nature, requires a set work process, or processes. In addition, using SOPs and associated policies ensures that each decision goes through the same process and is based on the same criteria. This results in decisions that are speedy, transparent, and consistent.

The Agency has put into place an SOP/policy initiative to ensure that staff plan and complete work using SOPs and policies. As part of this ongoing effort, it has established planning templates that are used for SOP and policy development. The Agency also has put in place the Policy, SOP, and QAPP Documentation Policy, that establishes that SOPs and policies should be documented separately. SOPs capture the collective knowledge on how best to implement a process. Policies are directives from management that are either derived directly from statutes and administrative rules, or are based on well supported (by science or law) or well established interpretation of statues or rules.

As stated in Part 1.4.1, the best way to improve a work product or decision-announcing-record is to improve the process that produces that product or record. The Agency has in place an ongoing effort to revise and improve existing SOPs, as well as to develop additional SOPs for use by each area of environmental activity (see Part 1.1.2). Its efforts to improve and expand its use of SOPs will:

- Promote efficiency & consistency;
- Help staff avoid known pitfalls;
- Make it easier to train new employees;
- Make it easier to track down the cause of a problem;

- Allow staff to develop the "best known method" for doing something and ensure that method is documented, shared, used consistently, and continually refined.

By putting into place the "Agency Policy, SOP, and QAPP Documentation Policy" the Agency has put several quality system components in place to ensure that SOPs are used by staff doing the work. These measures include:

- Conducting Agency-wide training on SOP development emphasizing that SOPs should be developed by the staff doing the work to ensure ownership and support for the use and improvement of documented work processes;
- Establishing content requirements for SOPs that include:
  - Work flow charts;
  - Definitions;
  - Identification of staff and managerial roles;
  - Identification of all necessary forms, software, or equipment that may be used to complete the process;
  - A detailed, step-by-step description of the process;
  - Any records management requirements;
  - Descriptions of any quality assurance or quality control measures and an identification of who reviews the work addressed by the SOP; and,
  - Citations of applicable references;
- Establishing that the various appropriate Section Chiefs and Branch Chiefs review and approve the SOPs developed by the staff doing the work;
- Establishing that Agency QA Managers review and approval draft SOPs to ensure their format is consistent with Agency standards;
- Establishing a template and requirements for documenting decision-making criteria in written policies and guidances that are to be used in conjunction with SOPs;
- Establishing that Branch Chiefs and Section Chiefs ensure that staff properly implements all applicable SOPs and policies.
- Requiring that all SOPs and associated written policies be reviewed bi-annually or sooner if the work process changes, or if the ongoing reviews of work products done by management as part of the existing Agency chain of review and approval indicate that particular work products need improvement;
- Requiring that written policies be revised biannually, or sooner if there are changes in decision-making criteria due either to enhanced interpretation of the available data or applicable law(s) or rule(s); And,
- Collecting, cataloging, and storing all SOPs from throughout the Agency in a centralized quality assurance library.

8.2. Identification of operations needing SOPs/technical documents

Ensuring QAPPs are developed used when needed:

The Agency has put into place a Policy, SOP, and QAPP Documentation Policy that requires the development, maintenance, and use of QAPPs in accordance with USEPA Order 5360.1 by setting out the following requirements:

- A Quality Assurance Project Plan (QAPP) is required for all work in which environmental data will be collected, evaluated, used, or reported, or which involves the design, construction, and operation of environmental technology used as part of a remediation activity;
- Grant managers shall consult individual grants to determine the requirements for project or program QAPPs;

- QAPPs shall be developed using USEPA's graded approach, which allows exemption from those elements of the QAPP format that are not applicable to the process being documented;
- When planning projects, staff must use the data quality objectives process as described in the "USEPA Guidance on Systematic Planning Using the Data Quality Objectives Process, USEPA QA/G-4, February 2006," or the approved systematic planning process described in the their respective branch QMP;
- Project managers shall revise previously approved QAPPs before a new data collection activity begins if the scope, parameters or methods change; and,
- Projects and/or operations with QAPPs in place must be managed and documented as specified in the QAPP, and project managers and grant managers executing a QAPP are responsible for identifying, and reporting to their Supervisor if there are any discrepancies between the written steps of a process in a QAPP and the actual steps taken to do the process.

Since USEPA -awarded grants require a QAPP if they involve the collection, evaluation, use, or reporting of environmental data, or involve the design, construction, and operation of environmental technology used as part of a remediation activity, the Agency has put into place a Grants Management Policy, A-018-OEA-07-P-R1, March 2007, that establishes the following QAPP-related requirements for Agency grant applications:

- If the grant involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or complied from computerized databases and information systems, a Quality Assurance Project Plan (QAPP) must be developed (as required by USEPA Requirements for Quality Assurance Project Plans USEPA QA/R-5 March 2001, part 2.1) by the Agency grant coordinator responsible for the grant (or other responsible designated staff from the program receiving the grant)
- If a grant requires a QAPP be fully implemented by Agency staff, a complete draft of the associated QAPP (consistent with the standards established in USEPA QA/R-5 March 2001) must be completed by the program project manager (or other responsible designated program staff), approved by the program project managers supervisor(s), and ready for USEPA Region 5 review; and
- If partial or full implementation of a grant requiring a QAPP is dependent upon a contractor, the program project manager (or other responsible designated program staff) must first prepare a preliminary draft QAPP that satisfies the requirements in the Agency's Policy, SOP, and QAPP Documentation Policy and the completed document must be submitted to the awarding agency within the timeframe specified in the terms and conditions of the grant agreement.

Ensuring SOPs are developed and used, when needed:

The Agency has put into place a required initiative to promote the further identification of routine operations needing approved process planning (SOPs). The Agency has required that each section (at IDEM, a section is a subset branch and there are approximately 15 branches and approximately 65 sections) that implements a discrete environmental activity not performed by another section submit to the Agency QA Managers a prioritized list of SOPs and policies that need to be updated or developed (See Part 1.1.2), Quality System goals, "Develop 10 SOPs per section by July, 2007".) (Note that some Agency activities are performed by more than one section. For example, the Air Permits Branch has four (4) sections that each perform the same tasks and the Air Compliance Branch has two (2) sections and staff in three (3) regional offices that all perform the same tasks.

The Agency SOP training (Part 2.1.1) states that identifying and prioritizing activities that need SOPS is the first, and one of the most important stages of SOP development. Agency

QA Managers and executive staff recommend that each section develop an environmental activities list that identifies all the activities it performs, and then build a list of SOPs needed for each activity. They further recommended that the list be prioritized based on:

- Extent of existing policy documentation;
- Extent and quality of existing SOP documentation;
- Procedural gaps revealed through flowcharting that identify the need for a particular SOP(s) or written policy(s);
- Staff input based on past experience ;
- Anticipated impact to work product and/or customer; and,
- Whether the process has characteristics that make it important to control.

It also is recommended in the SOP training that staff developing SOPs or policies to fill existing gaps in work process start by focusing on easier routine processes to establish expertise and confidence, before trying to develop more complex SOPs.

8.3. Handling of SOPs, QAPPs, and other technical documents

8.3.1. Development:

The Agency's Policy, SOP, and QAPP Documentation Policy establishes development, and content requirements associated with both QAPPs and SOPs. It also establishes content requirements for documenting policies used in conjunction with SOPs to produce the Agency's principle work products, decision-announcing-records.

8.3.2. Approval:

The Agency's chain-of-review and approval process relies on the expertise and experience of Agency managers (SCs, BCs, and ACs). That same chain-of-review is incorporated into the Policy, SOP, and QAPP Documentation Policy, which addresses the review and approval processes associated with policies, SOPs, and QAPPs. That policy also identifies which staff shall participate in the review and approval process for policies, SOPs, or QAPPs, and who shall sign these Agency QA documents.

In addition, some Agency QAPPs require USEPA approval, and in fact, IDEM defers to USEPA Region 5 Quality Staff regarding all QAPP approvals.

8.3.3. Change:

QAPPs must be revised before the scope, parameters, or method of a data collection activity may be changed. Similarly, grant or project managers executing a QAPP are responsible for identifying, and reporting to their section QA contact, any discrepancies between the written steps of a process in a QAPP and the actual steps taken to do the process.

8.3.4. Usage:

The Agency Policy, SOP, and QAPP Documentation Policy establishes policy, SOP, and QAPP development requirements. It also establishes that documents will be reviewed by Agency QA Managers and stored in a centralized location maintained by them on an Agency computer server that provides access for all Agency staff.

With Agency-wide access to all Agency quality system documents (SOPs, QAPPs, policies and other related documents), comes the expectation that all Agency staff shall use the appropriate quality system documents whenever applicable. Further, all quality system documents shall be available upon request to the public unless there is an overriding issue of confidentially. As stated in the Agency Policy, SOP, and QAPP Documentation Policy, failure to follow appropriate policies, SOPs, and/or QAPPs may result in disciplinary action.

9. Assessment and response

Purpose – To document how the Agency will determine the suitability and effectiveness of its implemented quality system and the quality performance of the environmental programs to which the quality system applies

9.1. Assessment

9.1.1. Assessment tools:

USEPA QA/R-2 lists the following tools, some of which are used by the Agency to assess its quality system: quality systems audits; management systems reviews; peer reviews; technical reviews; performance evaluations; data quality assessments; readiness reviews; technical systems audits; and, surveillance.

9.1.1.1. Quality system audit:

As stated in the Introduction, the IDEM Quality Management Plan (QMP) is comprised of separate, but specific branch-level "sub", or mini QMPs that are unified by a single, Agency-wide QMP that addresses those QA issues applicable to the entire Agency. The branch-level QMPs detail the more specific QA activities associated only within their respective branch.

Because the Agency QA Managers are not under the authority of any one of the branches, they are sufficiently isolated from the branch management hierarchy to act independently of them as they initiate quality system audits of each of the branch-level QMPs. This arrangement is consistent with "USEPA Requirements for Quality Management Plans, USEPA QA/R-2, Part 3.10 "Assessment and Response", that personnel conducting quality system assessments have: 1) a technical understanding of quality system features and requirements; 2) no involvement in the program being assessed; 3) adequate organizational freedom to access program components; and, 4) a commitment from management to review and act on assessment findings.

Concurrent with development of the IDEM 2007 QMP, the Agency QA Managers used a QMP template they first shared with USEPA Region 5 QA Managers in June of 2005, to perform a systematic and independent inventory and examination of the Agency and branch-level quality systems. The template required each branch to document system goals, resources, components, procurement practices, document management practices, computer usage requirements, project planning activities, and process implementation methods of the environmentally-related activities and actions performed by each branch within the Agency. This extensive examination provided the Agency with a thorough assessment of the quality activities associated with each Agency branch. It also provides a framework on which current and future evaluations of the effectiveness and suitability of each branches' quality system, and the overall Agency quality system, shall be based.

The quality system audit done by Agency QA Managers during development of the IDEM 2007 QMP, established that:

- IDEM has a viable quality system in place;
- There will be ample room for future improvement of the Agency's quality system; and,
- Agency QA Managers have the quality system expertise, the organizational independence, and the executive staff support to conduct future quality system audits.

That quality system audit served as a start-up of the Agency quality system. All future quality system audits of the IDEM Agency-wide QMP, and the Agency Branch QMPs conducted by the Agency QA Managers will use the process listed (Steps A-L) in Part 2.2.2., above.

9.1.1.2. Management Systems Review (MSR):

USEPA has the familiarity with the IDEM programs and the quality systems expertise to perform a thorough review of the IDEM Agency-wide Quality Management Plan (QMP) and associated supporting QA/QC documentation, or to review the various IDEM branch level QMPs. The Agency intends that USEPA Region 5 lead MSRs also will continue to be a key quality system assessment tool.

USEPA Region 5 and GLNPO QA Managers, in addition to approval of the IDEM QMP and subsequent revisions, will assess the implementation and effectiveness of the Agency's quality system through various means including, at a minimum, one on-site management systems review (MSR) during the effective approval dates of the QMP. USEPA assessment reports may identify findings which require corrective actions by the Agency. That in turn, may necessitate development or revision of procedures or revisions to Agency-wide and/or program QMPs. Other information provided by the Agency including the results of its annual internal QMP reviews, identifying the need for minor or major QMP revisions. Agency QAPPs also will provide additional means for USEPA Region 5 to assess the Agency's quality system.5.

9.1.1.3. Peer review:

Peer review of scientific data gathering or analysis by qualified staff with "expertise equivalent to those who produced the initial work product" is done on a regular basis. Each of the three (3) major media areas within IDEM the Agency (air, land, and water) has, as part of its organization structure, a science support staff with verifiable technical and/or scientific backgrounds. The central mission of these staff is to provide technical and scientific support for those staff that perform the core regulatory functions of the Agency: permitting, compliance, enforcement, and remediation.

Although there may be some overlap of responsibility for work products within each Agency science support staff group due to the small size of the branch staffs and the reliance on team work within the group, Agency staff doing peer review have an adequate degree of distance from the work product to be considered organizationally independent (consistent with USEPA QA/R-2, 3.10.). Because managers of science support staff both assign work, and assign peer review of the same work, they can assure some degree of independence between assignments to initiate work, and assignments to review it. In addition, managers too have that same "expertise equivalent to those who produced the initial work product" that qualifies them to review, in an independent manner, work they assigned to staff. This managerial level of expertise is consistent with the managerial review and approval process that is an essential throughout the Agency, as a tool for assuring quality control.

Additionally, the Agency Policy, SOP, and QAPP Documentation Policy, Part 6.3.2. further states that: "Staff that writes the QAPP may not also participate in reviewing the QAPP for final draft. Similarly, staff reviewing the QAPP shall not participate as authors. Agency QA Manager(s) shall participate in the review of each draft QAPP before final approval or before it is sent to USEPA for review and/or approval."

Branches that conduct peer reviews may further address the issue of independence from the final work product, as well as review techniques, practices, and policies in their respective QMPs.

The review of data sent to USEPA

The referenced branch SOPs will be incorporated into the branch QMPs. The quality assurance process for Agency gathered data going to USEPA is as follows:

- Resource Conservation and Recovery Act (RCRA) data entered by Office of Land Quality (OLQ) and Office of Compliance and Enforcement (OCE) staff into the Indiana RCRA Activity Tracking System (IRATS) and the Multimedia Enforcement Tracking System (METS) is manually reviewed weekly by the OLQ data steward.

A report of all newly entered data of the previous week is printed out and assessed by the data steward, who forwards any data that appear to be potentially inaccurate to the attention of OLQ and/or OCE managers and staff for verification. The data steward similarly notifies staff for historical updates.
Staff makes any updates or data corrections into IRATS and METS databases. The data steward then uploads the corrected IRATS and METS data into USEPA's RCRAInfo database.

National Pollution Discharge Elimination System (NPDES) related data provided by the Agency to USEPA for inclusion in the Permit Compliance System (PCS), Integrated Compliance Information System (ICIS), Enforcement and Compliance History Online (ECHO), and/or USEPA Envirofacts database is first reviewed by the IDEM Office of Water Quality (OWQ) Compliance Branch, Data & Information Services Section. The section uses three SOPS to ensure data quality (These three SOPs are currently being updated and will be provided at a later date.):

(1) The "Data Entry SOP" ensures the quality of NPDES data as it is initially entered into the ICIS database.

(2) The "NPDES Data QC SOP" describes methods used to regularly (monthly) check and correct data, and thereby further ensure the high quality of the Indiana NPDES data within the above mentioned databases. This regular review also diminishes the need to respond to concerns about incorrect data.

(3) The "Compliance SOP" is sometimes used to respond to, or follow up on questions from facilities regarding the quality of the data for their facilities as it appears in USEPA databases. If the Data & Information Services Section receives questions/comments from a facility or group of facilities about the data or compliance status, as it appears in one of the USEPA sponsored databases PCS, ICIS, ECHO, and/or Envirofacts, the appropriate Data Manager is notified (either directly or by the Section Chief). He/she will check the data (correcting it if necessary), using methods described in the aforementioned "NPDES Data QC SOP." If the data as presented in the database is correct, and it appears that a facility or group of facilities has violations/errors due to the NPDES facility management itself, the Data Manager will use the "Compliance SOP" in order to refer the NPDES facility to the appropriate Compliance Manager in the Compliance Section, for further attention.

- The air compliance-related data uploaded by IDEM to AIRS/AFS (Aerometric Information Retrieval System/AIRS Facility Subsystem) is subjected to several quality assurance reviews by IDEM Office of Air Quality (OAQ) staff, including:

  (1) Each month, OAQ runs a report in AFS that lists all the high priority violations (HPVs) that are open in AFS, and compares that AFS report to the Agency Multimedia Enforcement Tracking System (METS). The quality assured data is then hand entered into AFS.

  (2) Every 60 days, OAQ and OCE (the IDEM Office of Compliance and Enforcement) upload data from the IDEM ACES (Air Compliance Enforcement System) database into AFS to meet USEPA Minimum Data Requirements for Clean Air Act Stationary Source Compliance, and USEPA's Compliance Monitoring Strategy. Any uploaded data not accepted into AFS is listed on an "error report." OAQ then reviews each "error" in the report to determine which character did not match up with the AIRS format. If OAQ verifies that the data on the error report matches what is in the state ACES database, then that data is entered into AFS by hand. This is done for each error in the AFS error report.

  (3) When sources contact the OAQ data steward about errors in the USEPA Enforcement and Compliance History Online (ECHO) database; OAQ first searches the ACES database to verify that the source has correctly identified an error. If the source has correctly identified that there is an error in ECHO,

OAQ tries to correct the error in AIRS/AFS. However, if OAQ cannot access AIRS to correct the error, USEPA Region 5 is notified regarding the specific correction that needs to be made to the data in ECHO.

- The IDEM Drinking Water program transfers data to USEPA by way of the Safe Drinking Water Information System (SDWIS) databases. Data is uploaded from the Agency's "SDWIS-State" database to the "SDWIS-Fed" using an Extensible Markup Language (XML) schema. The data is then verified by USEPA and extracted for use in their databases, including Envirofacts. (www.epa.gov/safewater/dwinfo.html) and Safe Drinking Water Accession and Review System (SDWARS). The Agency's data is verified by the Drinking Water Branch and any validation errors identified by USEPA during the data transfer are reviewed and corrected.

9.1.1.4. Technical review:

Like peer review, technical review is done by Agency staff with technical expertise equivalent to or greater than those who produced the initial work product. As is the case with peer review, staff conducting technical reviews generally has an adequate degree of independence from responsibility for the final work product. Branches with programs that conduct technical review discuss their review techniques, policies, and/or practices in their respective branch-level QMPs.

9.1.1.5. Performance evaluation:

This assessment tool is not applicable for every branch or environmental activity throughout the Agency, but rather is used by some Agency environmental activity areas that rely on contracted services, especially contracted laboratory services. Branches that use such contracted services should state whether they use QAPPs under Part 1.4.3 of their respective QMPs. Laboratories and other contractors used by the Agency shall have Agency-required quality systems (or Quality Management Plans for all contractors that have a contract with IDEM equal to or greater than $100,000) in place for quantitative comparison (see 1.4.2 "all IDEM Professional/Personal Services Contracts require that contractors and their employees and subcontractors comply with all applicable licensing standards, certification standards, and accrediting standards.").

9.1.1.6. Data quality assessment:

Like performance evaluation QA assessments, data quality assessments are most appropriate for those activities that gather and/or use verifiable data, such as in OAQ Ambient Monitoring Branch (air quality science branch), OLQ Science Services and OLQ Remediation Services Branches (land science branches), and OWQ Assessment and Watershed Management Branches (water science services). Those branches using data quality assessment as one of their assessment tools address its use in their respective branch-level QMPs.

9.1.1.7. Readiness review:

The Agency does not generally rely on readiness review as an Agency-wide quality system-related assessment tool. However, some Agency programs that implement specific projects may use readiness reviews prior to the startup of the project. Those branches that use readiness review address its use in their respective branch-level QMP.

9.1.1.8. Technical systems audit:

The Agency does not generally rely on technical system audits as an Agency-wide quality system-related assessment tool, or for evaluating any Agency quality systems or quality system features on an Agency-wide basis. However, branches that use technical system audits as an assessment tool discuss its use in their respective branch-level QMP.

9.1.1.9. Surveillance:

Surveillance is a primary quality control component of the IDEM quality system and is used continually, throughout the Agency. The Agency has traditionally relied on a chain-or-review and approval by more experienced staff, most of whom also are managers. The Agency's managerial surveillance is the principle method of review to ensure the quality of the work product, which at IDEM is either a decision-announcing-record or a document supporting a decision. Surveillance also is the principle quality assessment tool to ensure the Agency's work is being done by staff with the proper training and experience, using the right equipment, the right methods, and the most appropriate data available.

Surveillance also is focused on the Agency quality system. Agency QA Managers are conducting continual, Agency-wide surveillance of all the various components of the Agency quality system, aided in this effort by the Agency's executive and managerial staffs, branch quality assurance (QA) coordinators, section QA contacts, and the SOP/QAPP committee members.

9.1.2. Frequency of assessments:

All IDEM branch QMPs will be reviewed at least once during the five year review cycle of the IDEM QMP. All other Agency policies will be assessed on the review cycles established by the Agency Policy, SOP, and QAPP Documentation Policy (policies and SOPs every 2 years, project QAPPs annually, and program QAPPs every five years).

In addition, the Agency relies on five (5) tools to establish a review cycle:

- First, the Agency QA Managers intend to conduct periodic assessments of the quality system components to ensure the continued application and expansion of quality system principles.
- Second, the Agency's Policy, SOP, and QAPP Documentation Policy requires periodic review and update of all Agency policies, SOPs, and QAPPs (time frames stated above);
- Third, program area managers will conduct an ongoing, real-time surveillance assessment of the quality of the work product during the management review that occurs as part of the existing approval chain. Significant problems with work products will trigger re-evaluation of any associated quality system tools. In such instances, the Agency does not intend that program areas await scheduled assessments and corrective actions, but instead recommends the immediate correction of problems discovered during real-time surveillance;
- Fourth, any USEPA Region 5 assessments, such as a management system review, which will continue to serve as a highly-valued critique of the Agency's quality systems, will be conducted on a timetable to be determined by USEPA Region 5; and,
- Fifth, USEPA Region 5 review and approval of Agency program QAPPs (or their USEPA -approved equivalent, such as a program lab manual).

9.1.3. Selection of assessment personnel:

All Agency program areas have substantial workloads associated with: 1) the core program work functions; 2) the ongoing development of SOPs, policies and other quality system tools; and, 3) self-assessment within the program areas. As a result, most program areas do not have available staff to participate in Agency-wide quality assessment efforts. Therefore, Agency QA Managers will serve as the primary quality system assessment for all Agency staff.

9.1.4. Assessment planning:

The Agency does not currently have a specific established assessment plan in place because some of the essential features of a set plan continue to expand and improve. Part 9.1.1,

demonstrates that the Agency has a reliable inventory of assessment tools available for use. As demonstrated in Part 9.1.2, the Agency also has several timetables under which future assessments will be carried out. Part 9.1.3, establishes that while initial assessments likely will be done by Agency QA Managers, there is potential for expansion of the pool of technically qualified and adequately independent quality assessors as the Agency's quality system further matures.

The planning and implementation of each future assessment will be documented in an assessment report that will be prepared and presented to both Agency executive and managerial staff.

9.2. Response

Responses to the findings of a quality system assessment are anticipated at several levels.

9.2.1. Corrective actions:

Corrective actions written and presented to the Agency from USEPA Region 5 and GLNPO QA Managers (such as from a management system review or QAPP assessment) are always a priority for IDEM executive staff. Either Agency QA Managers shall implement USEPA Region 5-recommended corrective actions through direct involvement at the Agency-wide level, or program area managers and branch QA coordinators and/or section QA contacts shall implement the USEPA Region 5-recommended quality system corrections with Agency QA Manager and executive staff input and oversight.

9.2.2. Dispute resolution:

Any disagreement by Agency managers (SCs, BCs, or ACs) or staff with respect to a corrective action recommendation from Agency QA Managers or USEPA Region 5 and GLNPO QA Managers will be mediated by Agency executive staff. Agency executive staff will take the lead in resolving any resource or policy issues that inhibit pursuit of corrective action measures by any Agency program area. Similarly, Agency executive staff could modify the assessment recommendation, or alter the quality system in a manner that would alter the Agency QA Managers' assessment, or impact the type of corrective action needed.

10. Quality Improvement

Purpose – To document how IDEM will improve its quality system

10.1. Point of contact

The Agency QA Managers are responsible for evaluating the quality system on a regular basis. They are also responsible for assessing the effectiveness of additional quality system improvements and for planning additional quality improvement activities. The Agency QA Managers will coordinate with executive staff and with branch level managers and branch QA coordinators to plan further improvements to the quality system.

10.2. Process(es) for continuous quality improvement

The review timetables established by the Agency Policy, SOP, and QAPP Documentation Policy promote a cycle of continuous improvement. Ongoing interaction with USEPA Region 5 and GLNPO QA Managers, along with annual USEPA reporting requirements and periodic management system reviews performed at IDEM by USEPA also will keep the Agency on course for steady, long term improvement of its quality system. In addition, quality system issues detected during the real-time surveillance that is inherent in the Agency's managerial chain of review and approval further ensures steady improvement of the Agency's quality system development, implementation, assessment, and improvement cycle.

10.3. Process(es) for preventing or ameliorating conditions averse to quality

10.3.1. Prevention of conditions adverse to quality:

The Agency's chain of manager approval will continue to serve as its primary deterrent to the erosion of the quality work methods that are needed to produce quality work products. The chain of approval traditionally has served to ensure that final work products are consistent with the mission of the Agency. The same chain of approval also will help to determine the effectiveness of existing and new quality system tools, SOPs and written policies in particular.

10.3.2. Identification of conditions averse to quality:

The chain of manager approval also will serve to detect problems with the quality system. Any perceived decline in the quality of the work products will trigger a review of quality system tools and methodologies. For example, if a work product does not meet established standards, it could be an indicator that management and staff should revisit and perhaps revise one or more of the written SOPs and decision-making policies upon which it was based. The tools to ensure quality work products – the QMP, SOPs, written policies, and QAPPs -- are gradually put into place at IDEM as a result of the Agency's commitment to expanding the quality system and bring standardization and widely accepted business practices into common use.

Quality system audits by the Agency QA Managers also will keep development of the Agency quality system on track. Similarly, management system reviews by USEPA Region 5 and GLNPO QA Managers, performed on a schedule to be determined by that them, also will help to identify problems, or gaps in the Agency's evolving quality system.

10.3.3. Correction of conditions adverse to quality:

The Agency intends that any quality system problems detected by the manager review process, Agency QA Manager quality system audits, or USEPA Region 5 management system reviews will be addressed within the timetables referenced above. Corrective actions will be implemented by the affected program. All corrective actions will be documented in the "History of Revisions" section of the affected SOP or policy. The Agency QA Managers will track program progress to ensure the effectiveness of quality system tools (primarily SOPs and policies) are addressed within the established timeframes, or at minimum, within a reasonable time after they are detected and reported.

In conclusion, continuous improvement of the IDEM quality system is the primary responsibility of the Agency QA Managers. This is reflected in:

A. Quality Assurance (QA) System Goals that include commitments to develop a centralized QA library for quick access by all Agency staff, institute QAPP development and assessment procedures, identify all Agency environmental data gathering and analysis activities, conduct internal QA assessments, and push the development of program area SOPs and their continual refinement (Part 1.1.3.);
B. A commitment to ongoing QA training (Part 2.1.4.);
C. The inclusion of the QAPP process into the Agency grants program, as documented in the Agency Grants Management Policy, A-018-OEA-06-P-R1, March 1, 2007, (Part 4.1.);
D. A requirement that contractors have QMPs and use QAPPs when appropriate (Part 4.1.);
E. The implementation of QAPPs, SOPs, and policies as Agency planning tools to improve work product, enhance staff performance, and further assure the use of QA principles, (Parts 7 and 8);
F. The use of multiple types of assessment tools to evaluate usage of QA principles and to provide analysis for further QA system improvement (Part 9);
G. The Agency QA Managers' commitment to work with USEPA Region 5 and GLNPO QA Managers' regarding their assessment of the Agency quality system during Management System Reviews (MSRs) (Part 9.1.1.2.);

H. Implementation of the Agency Policy, SOP, and QAPP Documentation Policy, A-050-OEA-07-P-R0, February 15, 2007, to ensure the proper development, content, approval, maintenance, usage, and storage of Agency policies, SOPs, and QAPPs;

I. Adherence to the document review, update, and re-approval of Agency policies, SOPs, and QAPPs, as required by the Agency Policy, SOP, and QAPP Documentation Policy, A-050-OEA-07-P-R0, February 15, 2007; and

J. Review of branch QMPs using the process described in Part 2.2.2.

These components of the Agency quality system, demonstrate a multi-approach commitment to continuous improvement of the IDEM quality system.

The Agency commitment to enhance and continuously improve its quality system already has been demonstrated by the manner in which the Agency QMP has been reorganized and expanded to better capture the detail of Agency QA activities at the branch and program area level, and by the thorough revision of Agency QA-related policies first put into place only a little more than a year before the submittal of the IDEM 2007 QMP for USEPA review.

11. Definitions

Data Quality Assessment: A statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

DQOs (Data Quality Objectives): The DQO process is a seven-step planning approach to develop sampling designs for data collection activities that support decision-making. This process uses systematic planning and statistical hypothesis testing to differentiated between two or more clearly defined alternatives.

Environmental Activity: A process (series of steps), or collection of related processes, that result in an internal or external work product or service, such as a permit, approval, license, inspection report, referral, or other IDEM work product.

Environmental Data: Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology used as part of a remediation activity. For USEPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

Environmental Data Operations: Work performed or activity conducted to obtain, use, or report information (including environmental data) pertaining to environmental processes and conditions.

Environmental Programs: Work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Environmental Technology: An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Graded Approach: The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

Information Quality Guidelines: IDEM's commitment to ensure information disseminated by the Agency is presented in an accurate, clear, complete, and unbiased manner.

Management: Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System: A structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review: The qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Peer Review: A documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

Performance Evaluation: A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Record: (From Indiana Code; IC 5-15-5.1-1) All documentation of the informational, communicative or decision-making processes of state government, its agencies and subdivisions made or received by any agency of state government or its employees in connection with the transaction of public business or government functions, which documentation is created, received, retained, maintained, or filed by that agency or its successors as evidence of its activities or because of the informational value of the data in the documentation, and which is generated on:

(1) paper or paper substitutes;
(2) photographic or chemically based media;
(3) magnetic or machine readable media; or
(4) any other materials, regardless of form or characteristics.

Quality: The totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

Quality Assurance (QA): An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Project Plan (QAPP): A formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. In other words, a QAPP is a 'blueprint' by which individual projects involving environmental data are implemented and assessed and how specific QA/QC activities will be applied during a particular project.

Quality Control (QC): The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

Quality Management: That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation,

documentation, and assessment) pertaining to the quality system. In other words, the difference between a Quality Management Plan (QMP) and a QA Project Plan (QAPP) is that a QMP describes an organization's quality system, i.e., its systematic approach to quality assurance, while a QAPP describes the necessary QA procedures, quality control (QC) activities, and other technical activities that will be implemented for a specific project or program.

Quality Management Plan (QMP): A document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

Quality System Audit: A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

Readiness Review: A systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Secondary Data: Secondary data (also known as acquired data) is data or information used for project implementation or decision-making which meet one of the following criteria:

1. Are compiled from other sources
2. Were originally collected for some other purposes
3. Are obtained from non-measurement sources such as computer databases, programs, scientific literature, and historical databases.

Standard Operating Procedure (SOP): A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks. (From: USEPA QA/R-2 May 2006 A-2)

Surveillance (quality): Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Technical Program: A process (series of steps), or collection of related processes, that involve the collection or analysis of quantitative data and result in an Agency decision (internal or external work product) or service.

Technical Review: A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Systems Audit: A thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

12. EPA List of Acronyms

List of Acronyms and Definitions

AA	Assistant Administrator
ANSI	American National Standard Institute

ARA	Assistant Regional Administrator (Region 5)
ARD	Air and Radiation Division (Region 5)
ASQ	American Society for Quality
ATRB	Air Toxics and Radiation Branch, ARD (Region 5)
CA	Cooperative Agreements
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act (Superfund)
CFR	Code of Federal Register
COR	Contracting Officer's Representative (Project Officer for Contract, Work Assignment Manager, Task Order Manager, Delivery Order Manager, etc.)
CMM	Contract Management Manual (EPA Directive 1900)
CRL	Central Regional Laboratory (Region 5)
CWA	Clean Water Act
DA	Deputy Administrator
DOJ	Department of Justice
DQA	Data Quality Assessment
DQO	Data Quality Objectives
DRA	Deputy Regional Administrator
ECAB	Enforcement and Compliance Assurance Branch (WPTD)
EDP	Environmental Data Operation
EDPA	Environmental Data Operation Activity
EnPPA	Environmental Performance Partnership Agreement
EPA	Environmental Protection Agency
EPAAR	Environmental Protection Agency Acquisition Regulations
EPS	Environmental Protection Specialist
ERB	Emergency Response Branch, SFD (Region 5)
EPCRA	Emergency Planning and Community Right-to-know Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FMFIA	Federal Managers Financial Integrity Act
FOIA	Freedom of Information Act
GDWB	Groundwater and Drinking Water Branch, WD (Region 5)
GIS	Geographic Information System
GLNPO	Great Lake National Program Office
GPS	Global Positioning System
HSWA	Hazardous and Solid Waste Disposal Act
IAG	Interagency Agreement
IEO	Indian Environmental Office (Region 5)

IMB	Information Management Branch
IRS	Intergovernmental Relations Staff (Region 5)
ITS	Information Technology Section
LUST	Leaking Underground Storage Tank
MSR	Management System Review
Must	denotes a requirement that has to be met
NCP	National Contingency Plan
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NEPPS	National Environmental Performance Partnership System
NERL	National Environmental Research Laboratory (formerly the Environmental Monitoring System Laboratory)
NPB	NPDES Program Branch, WD (Region 5)
NPDES	National Pollutant Discharge Elimination System
NPM	National Program Manager
NPO	National Program Office
OEI	Office of Environmental Information
OIA	Office of International Activity (Region 5)
OIG	Office of the Inspector General (OEA)
OIS	Office of Information System, RMD (Region 5)
OMB	Office of Management and Budget
OPA	Office of Public Affairs (Region 5)
OPA	Office of Policy Analysis (OPPE)
ORA	Office of Regional Administrator
ORC	Office of Regional Council (EPA)
ORD	Office of Research and Development
OSEA	Office of Strategic Environmental Analysis (Region 5)
OSWER	Office of Solid Waste and Emergency Response
PBMS	Performance Based Measurement System
PE	Performance Evaluation
PM	Project Manager
PMB	Program Management Branch, WPTD (Region 5)
PO	Project Officer
PPA	Performance Partnership Agreement
PPG	Performance Partnership Grant
PPN	Procurement Policy Notice (PPN 01-02, March 20, 2001)
PT	Proficiency Testing

PTB	Pesticides and Toxics Branch, WPTD (Region 5)
QA	Quality Assurance
QAAWRP	Quality Assurance Annual Report and Work Plan
QAC	Quality Assurance Coordinator
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QS	Quality System
QS	Quality Staff (Office of Environmental Information, OEI)
R5QARF	Region 5 Quality Assurance Review Form for Contract
RA	Regional Administrator
RAP	Remedial Action Plan
RC	Regional Counsel
RCRA	Resources Conservation Recovery Act of 1976
RDB	Regulation Development Branch, ARD (Region 5)
RMC	Resources Management Committee (Region 5)
RMD	Resources Management Division (Region 5)
RQAC	Regional Quality Assurance Core (Region 5)
RQAM	Regional Quality Assurance Manager
RQAT	Regional Quality Assurance Team (Region 5)
RRB	Remedial Removal Branch, SFD (Region 5)
SDWA	Safe Drinking Water Act
SFD	Superfund Division (Region 5)
Shall	denotes a requirement that is mandatory whenever the criteria for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.
Should	denotes a guideline or recommendation whenever non-compliance with the specification is permissible.
SOP	Standard Operating Procedure
SRO	Senior Resource Official
STPB	State and Tribal Program Branch, WD (Region 5)
SWDA	Solid Waste Disposal Act
TEP	Technical Evaluation Panel
TQM	Total Quality Management
TRI	Toxics Release Inventory
TSA	Technical System Audit

TSCA	Toxic Substance Control Act
UIC	Underground Injection Control
UICB	Underground Injection Control Branch, WD (Region 5)
USC	United States Code
UST	Underground Storage Tank
WAM	Work Assignment Manager
WD	Water Division (Region 5)
WECAB	Water Enforcement and Compliance Assurance Branch, WD (Region 5)
WMB	Waste Management Branch, WPTD (Region 5)
WWB	Watershed and Wetlands Branch, WD (Region 5)
WPTD	Waste, Pesticides and Toxics Division (Region 5)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

APR 17 2007

REPLY TO THE ATTENTION OF:
R-19J

Thomas W. Easterly, Commissioner
Indiana Department of Environmental Management
100 North Senate Avenue
Indianapolis, Indiana 46204

Dept. Of Environmental Management
Commissioner's Office
APR 24 2007

Dear Mr. Easterly:

On behalf of the United States Environmental Protection Agency (U.S. EPA) Region 5 and the Great Lakes National Program Office (GLNPO), I am pleased to provide approval of the Indiana Department of Environmental Management (IDEM) Agency-Wide Quality Management Plan (QMP) submitted with your letter dated March 9, 2007. The QMP documents IDEM's current quality system which encompasses environmental data operations delegated and/or financially supported by Region 5 and GLNPO. The QMP demonstrates your commitment towards building a strong quality system infrastructure for planning, implementing and assessing your environmental data.

The approval of this QMP will be valid for up to five years from the date of this letter. Revision of the QMP by IDEM may be required during the five year period based upon: periodic assessments by Region 5 and GLNPO, your annual internal reviews and/or significant changes in your organization, resources or scope of mission. At a minimum, a revised and updated QMP must be submitted for Region 5 and GLNPO review and approval six months prior to the expiration of the five year approval period.

IDEM will continue to submit project and program Quality Assurance Project Plans (QAPPs) to Region 5 and GLNPO for all applicable environmental programs including Superfund pre-remedial and remedial activities under 40 CFR 35 Subpart O and Superfund removal program under 40 CFR 300. It is my understanding that IDEM's submissions during the coming year to Region 5 Waste, Pesticides and Toxics Division (WPTD) will include inspection program QAPPs for IDEM's Leaking Underground Storage Tank, RCRA Subtitle C, TSCA PCB and Asbestos programs.

The U.S. EPA is required to assess the implementation of approved quality systems as well as individual extramural agreements which provide financial assistance. To facilitate these assessments, I request that IDEM provide information each year to Region 5 which:

- identifies any minor revisions needed and/or incorporated into the QMP during the preceding year;

- confirms that the quality system approved by U.S. EPA is still in effect; and
- identifies QAPPs prepared by IDEM for environmental programs encompassed by the QMP.

My appreciation is once again extended to your staff for their efforts to not just revise your QMP, but to build a deeper understanding of the importance of quality assurance throughout IDEM. In particular, I want to thank David Parry, Niles Parker and Scott Nally for their leadership, management support and coordination with U.S. EPA.

If you have any questions, please contact me, or have your staff contact Kevin Bolger, Regional QA Manager, at (312) 886-6762 or Louis Blume, GLNPO QA Manager, at (312) 353-2317.

I look forward to our continued partnership in assuring the quality of environmental data as the basis of our decisions.

Sincerely,

Mary A. Gade
Regional Administrator

Enclosure